



**FOREIGN
AFFAIRS AND
TRADE**



the Australian Government's overseas aid program

Module One

Introduction to Intellectual Property Law

**Intellectual Property and Biotechnology:
A Training Handbook**

Contents: Module One

1.1	OBJECTIVES FOR MODULE ONE	2
1.2	WHAT IS INTELLECTUAL PROPERTY?	3
	<i>patents</i>	
	<i>plant breeders' rights</i>	
	<i>trade secrets (undisclosed information)</i>	
	<i>trade marks</i>	
	<i>industrial designs</i>	
	<i>copyright</i>	
1.3	ENFORCING INTELLECTUAL PROPERTY RIGHTS	24
1.4	IP & THE LIFECYCLE OF A NEW PRODUCT	25
1.5	WHY HAVE INTELLECTUAL PROPERTY RIGHTS?	26
1.6	WHAT IS THE INTERNATIONAL FRAMEWORK FOR INTELLECTUAL PROPERTY?	30
1.7	SUMMARY - MODULE ONE	38
1.8	GROUP EXERCISES - MODULE ONE	39

1.1 Objectives for Module One

This Module provides an introduction to:

- the different types of intellectual property rights relevant to biotechnology including patents, plant breeders' rights, trade secrets, trade marks and geographical indications.
- various rationales for the intellectual property system
- the international intellectual property treaties relevant to biotechnology including:
 - the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
 - the Paris Convention for the Protection of Industrial Property
 - the Patent Cooperation Treaty (PCT)
 - the Budapest Treaty for the Deposit of Microorganisms
 - the Strasbourg Agreement Concerning the International Patent Classification
 - the International Convention for the Protection of New Varieties of Plants (UPOV)
- other international agreements relevant to biotechnology including:
 - the Convention on Biological Diversity (CBD), and
 - the Food and Agriculture Organisation (FAO) Treaty on Access to Plant Genetic Resources for Food and Agriculture.

1.2 What is Intellectual Property?

Intellectual property is a cluster of legally recognized rights associated with innovation and creativity – the works of the mind, as against physical products, land and other tangible resources. Even though it is intangible, intellectual property (IP) is often recognized as



personal property, to be sold and traded like other forms of property. But national laws normally don't define 'intellectual property' as a single property right. Instead, 'intellectual property' is used as a convenient general term describing a range of distinct legal rights. Within this spectrum, intellectual property rights can be very different from one another, in their subject matter, in the way they are defined, administered and enforced, and in the way they impact on other people. The general concept of 'intellectual property' is usually taken to cover specific rights relating to:

- patents
- trade marks
- trade secrets (or undisclosed information)
- copyright and rights related to copyright (such as rights of performers, producers and broadcasters)
- plant breeders' rights
- industrial designs
- integrated circuit designs
- geographical indications

'Industrial property' is a term used specifically for patents, designs and trade marks, in contrast to copyright and the related rights of performers, broadcasters and producers. You might also see the terms *intellectual capital* and *knowledge capital*. These terms are generally used to describe the intangible, but often highly valuable, assets of business enterprises that are embodied in the know-how, skills and specific knowledge of their personnel. This may include the material technically recognised as intellectual property (such as the patents and trade marks owned by a company). It also includes the background knowledge and capacities that make for a successful enterprise, which is not clearly defined or subject to specific legal protection. Intellectual capital can be very roughly measured by the difference between the market's valuation of a company (the value of all its stock on the stock exchange), and the value of its tangible assets - cash, other financial assets, physical property, goodwill, equipment and the like. Unlike 'intellectual property,' intellectual capital is not a specific legal term, although in some writings, the two terms are used in place of each other.

'Intellectual capital' and 'knowledge capital' can also refer to a society's or a community's collective intellectual resources, including its research capacity, its technological skills and its traditional knowledge. In recent years, increasing attention has been paid to the role of intellectual property and intellectual capital in economic and social development, but the idea is not new, as is illustrated by the following quote, from *The National System of Political Economy*, written by the German economist Friedrich List in 1841:

The present state of the nations is the result of the accumulation of all discoveries, inventions, improvements, perfections and exertions of all generations which have lived before us: they form the intellectual capital of the present human race, and every separate nation is productive only in the proportion in which its has known how to appropriate those attainments of former generations and to increase them by its own acquirements.

The value of intellectual capital can be extremely high, both for a society and for individual companies. Increasingly, the largest companies are defined by high levels of intellectual capital, both in the form of specific intellectual property rights and as informal kinds of know-how and knowledge.

One estimate of the intellectual capital in the world's most valued companies in 1997 is as follows:

Company	GE	Shell	Microsoft	Exxon	Coca-Cola	Intel	Nippon	Merck	Toyota	Novartis
Market value (\$bn)	222	191	160	158	151	151	146	121	117	104
Equity (\$bn)	34	77	11	44	7	19	43	13	46	22
Intellectual capital (\$bn)	188	114	149	114	144	132	103	108	71	82

Some formal definitions

The terms *intellectual property* and *industrial property* can often be used in a very general sense, but they do have specific legal meanings. Perhaps the most important definitions are given in the key international treaties on the subject.

The World Intellectual Property Organization (WIPO) is the United Nations specialized agency responsible for international cooperation on IP. *The Convention establishing WIPO* defines the scope of this cooperation in general terms, beyond the precise legal rights defined in national laws. The Convention defines *intellectual property* as including the rights relating to:

- literary, artistic and scientific works;
- performances of performing artists, phonograms, and broadcasts;
- inventions in all fields of human endeavor;
- scientific discoveries;
- industrial designs;
- trademarks, service 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.

For the purposes of the World Trade Organization (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, "intellectual property" is given a more limited application. It refers only to those categories of IP right that are explicitly covered in the Agreement's provisions on copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits and protection of undisclosed information. A copy of TRIPS is provided at *Annex One*.

The Paris Convention for the Protection of Industrial Property defines its subject matter in general terms:

The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition. Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.

Intellectual property rights (IPRs) are designed to protect the products of creative and inventive endeavours, and distinctive marks for traded goods and services. The grant of an IPR generally involves a trade-off, and some form of reciprocal obligation on the part of the right holder. For example, as a condition of receiving and maintaining a patent, inventors are required to make public details of their invention and may be required to ensure that the benefits of the invention are made available to the public on reasonable terms. Intellectual property rights form part of a nation's policy to encourage innovation and dissemination of knowledge, and are therefore intended to balance the interests of the inventor or originator with the broader needs of society.

This policy consideration is recognised in, and underscores, the TRIPS Agreement:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

While different types of IPRs, such as patents and copyright, developed separately, they all set out to achieve this same objective of a balance of interests that promotes general welfare.

Some general principles

The move towards international cooperation on IP originated in the limited recognition of foreign claimants' interests in national IP systems. It was often difficult or impossible for foreigners to gain effective intellectual property rights in many countries. The problems this caused, and the difficulties in trade relations between countries, were obvious as early as the 19th Century.

This led to general recognition of the principle of 'national treatment.' A country that applies the principle of national treatment agrees to extend to foreigners at least the same entitlements and benefits it provides to its own nationals. For instance, this means that a foreign patent applicant receives at least the same treatment as nationals in the patent application and examination processes, and pays the same fees to the patent office. National treatment in intellectual property is recognised in international treaties – including the first major multilateral agreements on IP, the Paris Convention (on industrial property) of 1883, and the Berne Convention (on copyright) of 1886.

TRIPS is today an important international treaty on IP, providing a framework for an harmonised international system of IP rights, building on the framework created especially by the Paris and Berne Conventions and a number of other agreements. TRIPS applies the principle of national treatment over a wide range of IPRs, which ensures equitable access to the IP systems of other countries. This means, for example, that an Indonesian national who has developed an invention or created an artistic work enjoys rights and privileges in most other countries at the same level of nationals of those countries.

TRIPS also provides for detailed standards on the substance of IP law. For instance, it specifies that computer software should be protected by copyright, and that patent rights should be available for a period of at least twenty years. It also specifies principles that should apply to administering and enforcing IPRs, and makes use of the WTO's dispute settlement system to resolve disputes. Because most people using this training material will be working in countries where the TRIPS standards either apply already or are being put into place, this material refers to the standards set out in TRIPS when discussing IP rights.

PATENTS

Patents are limited rights based on a claim that a new technological invention has been created and fully communicated to the public. Essentially they put a fence around territory which is claimed to be an entirely new contribution to human technological knowledge. It is a fundamental principle of patent law that no patent should give rights to prevent people from using existing knowledge or technology that is already available to the public at the date of the patent. In other words, the fence should not be put around terrain which is already public domain, or which belongs to someone else. It should only cover terrain that is genuinely new, and indeed would not have existed without a significant inventive contribution by the inventor. Governments can require,



as a condition of granting the patent right, that other interested parties should have reasonable access to this terrain – so the fence is not an absolute barrier, and others can enter the patented terrain for research, education, and other public interest needs. Governments can also compel the patent owner to give others access to this territory – a ‘compulsory licence’ which, in effect, requires sections of the fence to be lowered – in certain cases when the public benefits of the new invention have been unduly restricted

Patents rights are only available as the result of a positive decision to grant a patent, and this is usually preceded by some form of examination and check that the claims for patent protection are valid and legitimate.

What is protected by patent law?

Patents do not cover abstract ideas or theories, but are intended to cover specific technical solutions that have some practical application, use or benefit. A patent is generally available for an eligible *invention*. Quite what constitutes an ‘invention’ for the purposes of getting a patent is a matter of some debate and legal uncertainty, and there are differences between the legal approaches taken in different countries.

Patents can cover new products (such as a new polymer or a new ceramic material), processes that create these new products (such as the method required to create the new polymer), new processes for producing existing products (such as a more efficient way of producing glass), and new processes generally (such as a new method for applying fertilizer to a crop). Often a single patent can cover several different products and processes as well - provided they are expressions of the same basic inventive concept.

For example, one patent which has been widely debated, US patent 5,663,484 entitled *Basmati rice lines and grains*, included claims for:

- a rice plant with certain defined characteristics, defined in several different ways
- a seed produced by this rice plant
- a rice grain derived from that seed.
- a progeny plant of the claimed rice plant
- a rice grain with characteristics corresponding to the claimed plant
- three related methods for selecting a rice plant for breeding or propagation

In all, in this patent, the claimed invention was covered by 20 inter-related claims, some containing more detailed versions of broader claims. The patent document describes in some detail how all of this disparate claimed material is linked to the same underlying inventive concept, relating to a breeding process guided by associating the ‘starch index’ with desirable qualities of rice. It also describes the background to this claimed invention, and gives details of the research and breeding processes that led to it. This patent is considered further in the case study at the end of *Module Two: Intellectual Property and Biotechnology*.

EXAMPLE OF AN INVENTION – CONCEPTION AND REDUCTION TO PRACTICE

Ideas are easy to come by but reduction to practice is an arduous but inspirationally rewarding matter
- Buckminster Fuller.

Say you are a biotechnology researcher, and you have come up with an idea for a new way of using a certain class of bacteria to treat organic waste. Based on its general properties and after some speculation on your part, you suspect that in the right conditions at least some of these bacteria could process waste into a stable by-product that would be a useful fertilizer. So far, you're not sure whether this idea will work in practice or how to put it into effect on a large scale. You might also need to work out which particular bacterium within the general class is going to achieve the desired outcome – and you may even need to modify the bacteria to make them more effective. Your original idea may be valuable, and potentially a major benefit both for the environment and for agriculture. But it probably wouldn't be eligible for a patent, because a patented invention has to be a tangible outcome, not scientific speculation or an exercise of the imagination.

Patents generally require that the invention as claimed be useful or functional, and a description of how it can be put into practice. A famous US Supreme Court decision stated that:

... a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

Patent law in most countries requires an invention to be something that has a clear practical outcome. For example, US patent law distinguishes two stages in developing an invention that can be protected by a patent - the *conception* of the invention, and its *reduction to practice*. Once your research has proceeded to the point where you are reasonably confident that the idea can be put into practice, and you have developed a way of putting it to work, then it might be eligible for a patent. In this case, you might be able to obtain a patent for the resulting method for treating organic waste, and possibly for fertilizer produced by that method. Your patent would essentially cover the technical breakthrough – of conceiving of its possible use in waste treatment, and of working out how to apply this in practice. You would not normally be able to patent the relevant bacterium as such, because it would already be a known thing – however, if you used genetic engineering to create a completely new bacterium that was especially useful for your application, this microorganism might be eligible for patent protection in its own right.

Just because you come up with this new idea, and worked out how to put it into practice, you are not automatically entitled to get patent rights. To get a patent, your method would need to be truly new or novel (it would not be novel if you or someone else had already published a report on waste treatment using these bacteria before you tried to get a patent). Your method would also have to be more than an obvious thing to do based on the general background of technology (for instance, if it was already known that a very similar kind of bacteria was useful in achieving the same objective, and people working in the field would routinely turn to your bacterium when trying to solve this problem).

Your invention would also have to be genuinely useful in achieving the benefits you claim for it – you might not get a valid patent if you claimed patent rights over a wide range of bacteria, when only a few bacteria within that scope actually worked properly. You might also need to address concerns that exploitation of your method was not harmful to the environment, and was consistent with public order and morality.

Conditions for patentability

Not every new product or research outcome qualifies as an ‘invention.’ And it’s not enough just to have created an ‘invention’ to be eligible for a patent. It has to be an invention that passes certain legal tests – the tests for ‘patentability.’ So the patent law of most countries



includes three basic criteria for determining whether a claimed invention is eligible for a patent. These are termed the conditions for ‘patentability.’ The TRIPS Agreement expresses these conditions in a way that is now widely used in national laws. TRIPS specifies that patents should in principle be available for any inventions, whether

products or processes, provided that they are:

- new (or ‘novel’);
- involve an inventive step (or are ‘not obvious’); and
- are capable of industrial application (or have ‘utility’).

These requirements were only spelt out in a fully international treaty for the first time in the TRIPS Agreement, but they were already common to almost all national patent law in some form, and overlap with the underlying definition of ‘invention.’ These requirements have been applied in one way or another over centuries of patent law, in order to limit the application of patents to those particular kinds of invention which have the potential of introducing a tangible benefit to society. As a result, not all ‘inventions’ are patentable. These requirements are discussed in more detail in *Module Two: Biotechnology and Intellectual Property*.

Patent law often provides for exceptions to the kind of subject matter that can be covered by patents (‘patentable subject matter’). These exceptions relate to material that might be a patentable invention (meeting the general criteria for patentability), but which are still excluded as appropriate subject matter for patents. This is usually due to a legislative decision not to extend patent protection to certain specific classes of subject matter out of concern for other policy objectives. For example, TRIPS provides for exclusions from the scope of patentable subject matter:

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.

TRIPS also gives the option of excluding other forms of subject matter 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.

For example, a country could decide that, even though a new surgical method was an important invention, and it was new, had an inventive step and was useful under its patent law, it would still not grant patent protection to that invention. There may be policy concerns that patents on surgical methods could delay or impair the delivery of medical treatment, and the legislators might decide that these considerations outweigh the benefits of patent protection in this area.

DIFFERENT APPROACHES TO PATENT EXCEPTIONS

As a result of differing policy approaches to the scope of subject matter for patents, national patent laws express different requirements for patent eligibility. For instance, the Intellectual Property Code of the Philippines excludes the following from patent protection:

- Discoveries, scientific theories and mathematical methods;
- Schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;
- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods;
- Plant varieties or animal breeds or essentially biological processes for the production of plants or animals. This provision shall not apply to micro-organisms and non-biological and microbiological processes.
- Aesthetic creations; and
- Anything which is contrary to public order or morality.

The People's Republic of China's 1992 Patent Law currently specifically excludes patents on:

- Scientific discoveries;
- Rules and methods for mental activities;
- Methods for the diagnosis or for the treatment of diseases;
- Animal and plant varieties;
- Substances obtained by means of nuclear transformation.

The law of the Republic of Korea provides that 'inventions liable to contravene public order or morality or to injure public health shall not be patentable.'

This kind of provision (which is found in similar forms in most national patent law) specifies that even if an invention meets all the necessary standards – for example, even if a method of medical treatment is an invention which is truly novel, has a clear inventive step, and is definitely useful, it could still be denied patent protection for broader policy reasons.

What rights does a patent give?

Patent rights are limited, exclusionary rights. That is, they permit a patent owner to exclude others from making use of, or producing the claimed invention for a limited time, especially in a commercial context. This does not necessarily exclude the use of the patented invention for research or educational purposes, use by the government, or use in the context of public need, such as in a national emergency. The patent right is not a positive right - it does not necessarily entitle the patent owner to carry out the invention. For example, if you invented and patented a new pharmaceutical treatment to cure diabetes, you would still need to go through the normal regulatory approval required for any new drug before you could sell the pharmaceutical. If you invented a new explosive compound, you could not make or sell the explosive if this contravened industrial safety laws. Or if you are granted a patent on a seed for a genetically modified crop, this doesn't entitle you to sell the seed or commercially farm it, as the patent right does not overrule any environmental, health or consumer protection laws that can forbid

or regulate your use of the crop. In short, if you are granted a patent for an invention, this does give you the right to prevent others from commercially using your invention - but it doesn't automatically mean that you can use it commercially yourself.

TRIPS has to some extent harmonised the nature of the patent right, specifying that a patent on a product gives the right to prevent others from the unauthorized making, using, offering for sale, or selling the product, and from importing for those purposes. It provides for similar rights relating to patented process and products obtained directly by that process.

Patent rights are *territorial* – they are granted by national authorities with application in the national jurisdiction only. There is no such thing as a ‘world patent.’ A Canadian patent has no legal effect in Malaysia, and a Malaysian patent has no effect in Canada. So a Malaysian business can make free use of a technology described in a Canadian patent if there is no corresponding Malaysian patent right. (They would need to check whether other IPRs might apply – including earlier patents with broader scope, or other rights such as plant breeders rights, copyright or design protection.)

For more detail about how researchers and their commercial partners can benefit from IP rights please see: *Module Ten: Case Studies on Commercialising Research*. Patent rights do not guarantee the commercial success of an invention but they can assist. Patent rights do not automatically guarantee that a patent owner can use their invention. For more information on this matter see the section on “Freedom to Operate” in *Module Eight: Researching and Intellectual Property Rights*.

Patents and technology disclosure

Disclosure of inventions is at the heart of the patent system. Patent rights are granted to inventors to encourage research, development and innovation in industry. The patent protection only lasts for a limited time, normally set at 20 years. In return for these time-limited rights, the inventor must disclose details of how to work the invention so that it can be freely used by the public at the end of the term of the patent. It also normally means that other researchers can use the invention in their research, and that the invention is available for educational purposes, even while the patent right is still in force. This technical disclosure – a description of how the new technology can be put into practice - is provided in a patent specification.

These specifications are lodged at patent offices as part of the patent application, and are normally made available to the public 18 months after the application is filed. These specifications are an invaluable source of technical information. Patent offices are increasingly putting this information in electronic databases, and it is now possible to access much of this data directly by the internet.

TRIPS clarifies that the obligation to disclose the patent is a firm international standard. It requires that an applicant for a patent must disclose details of their invention. This disclosure must be clear and complete enough to enable the invention to be carried out. TRIPS also indicates that national patent laws can also require that a patent applicant should indicate the best mode for carrying out the invention known to the inventor. In line with this, patent laws generally require a detailed technical description of an actual functioning product or process that embodies the invention.

How do you get legal protection for patents?

Patents are granted through the national patent office, such as the Indonesian Directorate General of Intellectual Property Rights, the Mexican Institute of Industrial Property, IP Australia, the US Patent and Trademark Office, or the Japanese Patent Office. The process normally requires lodging an application accompanied by a detailed description of the invention, and a fee. The application process for patents is discussed in *Module Three: Reading a Biotechnology Patent and the Patent Process*. Under various regional arrangements, a regional authority grants patents with legal effect in participating countries: these systems are currently available in Europe, Eurasia (covering many countries of the former Soviet Union), and Africa.

Because patent rights are part of national law, and apply only in the country where they are granted, you have to apply separately for each individual country where you want to protect your invention (or in the regions where a regional system exists). You then have to comply with each country's or region's patent process to receive a patent. The Patent Cooperation Treaty (PCT), discussed below in more detail, allows for an international application to be made for a patent in different countries – this system simplifies the initial application process and reduces formalities, but doesn't replace the eventual need for individual national or regional patents.

Individual countries (and in a few cases, regions) grant patent rights which only apply to their own jurisdiction. So if you discover a US, Japanese or European patent which is not registered in your own country, you can legally make use of the patented invention in your country (and anywhere else where the same invention is not covered by a valid national patent), free of any legal constraint. You could, for example, make and sell a patented product for your own domestic market and for export markets, provided only that you did not export the patented product to one of those countries where the patent is in force.

Who owns patent rights?

Patents are registered in the name of their owners (often described as the 'patentee,' 'patent holder' or 'assignee'). This could be the inventor, but is often another person, company or institution.

An inventor can apply for a patent and if their application is successful they will be the patent owner. However, the individual inventor generally doesn't own the patent that is granted on their invention. This can occur if an inventor who is also the patent owner decides to sell the rights to the patent and assigns the rights to the purchaser. More frequently, the patent concerns an invention made by an employee in the course of their duties. A lot of research is conducted by employees who use the facilities of their employers. The general rule is that an invention made by employees in the course of their normal duties becomes the property of the employer, unless there is explicit agreement to the contrary. This issue arises, for instance, in relation to employee researchers in research institutes, universities and corporate research organisations. To avoid dispute over who owns the inventions created by employees, employment contracts often provide for employers to own the inventions created by their employees. If an employee wants ownership rights over their invention they usually would need to negotiate with their employer for such a right. However, the patent law of a number of countries provides employees with an entitlement to specific rewards in recognition of the economic benefits of their invention. *Module Eight: Researching and Intellectual Property Rights* looks at some of the issues that are relevant to the researcher.

How long do patent rights last?

The term of protection for patents is limited – in most cases, it runs for 20 years from the date the application is filed with the patent office. But the grant of a patent does not mean that it will automatically stay in effect for a full 20 years. In most countries, patent offices require regular fees to keep the patent in force, and these fees often rise during the life of the patent. When maintaining patents is not commercially viable, then many patents lapse due to the non-payment of fees and therefore fall into the public domain much sooner than the 20 years. Another reason for not paying regular fees is that the patented technology may soon become outdated and obsolete, and it is simply not worth continuing to pay for the patent. A change in company direction, or liquidation, can lead to patents being abandoned. In some cases, patents can also be partially or fully cancelled as a result of legal challenge. In general, don't assume that a patent has legal effect – before making any major decisions based on the apparent existence of a patent right, you should always check its current legal status to see whether it has lapsed or been cancelled. Some countries allow for extensions to the term of patents when there has been a long delay in bringing the patented invention – this arises especially for pharmaceuticals. Because of the length and rigour of testing and approval processes for new pharmaceuticals, the patented product might only reach the market place late in the life of the patent, so that some extension of this term is considered justified.

PLANT BREEDERS' RIGHTS

Plant breeders' rights (PBRs) give plant breeders the right to protect new varieties of plants – so you may also see them described as plant variety rights (PVR). These rights are distinct from patent protection, and are focused on the specific needs and interests of the plant



breeding and propagation process, originally based on traditional plant breeding methods. The nature of the protected subject matter and the scope of the right itself are therefore linked to the specific nature of plant breeding, and the way plant varieties are exploited. The protection only applies to new plant varieties as such, which are generally defined as the

lowest level of taxonomy (or classification) within the plant kingdom – that is, plant varieties are distinct variations within a given species.

Specific plant breeders' rights date back to 1930 when they were first granted in the US under the Plant Patent Act (although US plant patents are significantly different from most plant breeders' rights systems). Subsequently plant variety rights systems were created in other countries, as a form of protection separate from the patent system. Proposals for international harmonization of these systems culminated in the negotiation, in 1961, of the International Convention for the Protection of New Varieties of Plants (the UPOV Convention). The UPOV Convention is not a system of legal protection in itself, but an agreed level of harmonization and cooperation between national authorities. For instance, the UPOV Convention provides that rights over a new plant variety should include certain exclusive rights over the propagating material of the protected variety. Seeds of a new variety are an example of propagating material. The UPOV rights include rights over the production, reproduction, sale, export and import of propagating material for protected plant varieties.

The TRIPS Agreement only provides very general obligations in relation to the protection of new plant varieties. TRIPS requires that plant varieties must be protected by patents, or by a separate 'sui generis' system, or by both. (A *sui generis* system is an individual system for a particular purpose – unlike the patent system which covers general technology. Another *sui generis* IP system is the specific protection of integrated circuit layout designs.) TRIPS does not directly specify what the *sui generis* alternative needs to look like. Most countries have adopted some form of PBR or PVR system along the lines of the UPOV Convention, although this is

not specifically required under TRIPS. Some countries allow for dual patent and plant breeders' rights protection while other countries do not. Some commentators have explored alternative possibilities for *sui generis* plant variety rights, although in practice, systems based on the principles of the UPOV Convention are common in developed and developing countries.

What is protected by plant breeders' rights?

PBRs or PVRs protect a new plant variety. In the UPOV system, eligible plant varieties must be:

- distinct from other varieties;
- uniform (i.e. a single crop of the new variety must demonstrate the same characteristics); and
- stable (i.e. subsequent plantings of the variety must demonstrate the same characteristics as the parent crop).

These requirements are usually summarized as the 'DUS' requirements (an acronym for Distinct, Uniform and Stable.)

EXAMPLES - PLANT BREEDERS' RIGHTS PROTECTION OF A NEW VARIETIES OF FRUIT

The Japanese National Institute of Agrobiological Resources, Tsukuba, Japan, applied in Australia in 1997 for plant breeder's rights on a variety of the Japanese Pear (*Pyrus pyrifolia*), called Gold Nijisseiki. Protection for this variety had already been applied for in Japan, the USA, New Zealand and the Netherlands.

The detailed description of this variety that was prepared in the course of the application and published for public scrutiny described the origin of the variety: 'Gold Nijisseiki was bred through deliberate mutation of nursery stocks of the variety *Nijisseiki* and selected for strong resistance to black spot disease.' It then describes how its properties compare to those of the 'closest comparator,' namely the original variety *Nijisseiki*. It shows the results of field tests on resistance to black spot disease as:

Gold Nijisseiki	0% fruits infected	5-7% leaves infected
Nijisseiki	58% fruits infected	90% leaves infected

The official publication of this application also includes a colour picture of the two varieties showing their respective resistance to Black Spot. The resistance to this disease is one aspect of the 'distinct' quality of the new variety. This property of disease resistance would have to appear uniformly across a multiple crop of the pear, and would have to appear stably in successive generations.

Another system for protecting new plant varieties is the United States 'plant patent' system. US Plant Patent number PP008983 covers the banana plant known as FHIA-01, in the name of the *Fundacion Hondurena de Investigacion Agricola* (The Honduras Foundation for Agricultural Research). The new banana plant is described as having the following advantages over existing plants (with particular reference to an earlier variety known as Cavendish):

- High level of resistance to both the yellow Sigatoka leaf spot disease (*Mycosphaerella musicola*) and the black Sigatoka leaf spot disease (*Mycosphaerella fijiensis*).
- Practical immunity to both races 1 and 4 of Panama disease (*Fusarium oxysporum* f. sp. cubense).
- A strong root system, which makes it a hardy plant under marginal water and soil conditions.
- Cold tolerant - plant remains green under cold conditions which cause the reference "Williams" Cavendish variety to turn a yellowish color.
- Excellent green life of fruit after harvest which renders it suitable for export.
- Sliced or diced green and ripe fruit does not oxidize to an unsightly brownish color as does the fruit of the Cavendish export clones.
- Pleasant slightly tart flavor when ripe.
- Peel of harvested green fruit turns yellow when left to ripen under ambient conditions without ethylene treatment.

How do you get legal protection for plant breeders' rights ?

Like patents, PBRs are granted through a central registry, normally a dedicated plant breeders' rights office. A breeder seeking PBRs is required to lodge a specification to establish the distinctiveness of the plant variety being claimed. Colour photographs of the new variety may be included in the specification. Details of actual trials are also usually required. Further, there may be a requirement to conduct an independent trial specifically to determine whether the claimed variety meets the DUS criteria.

How long does plant breeders' protection last?

Like most intellectual property, the term of protection for PBRs is limited. UPOV provides that the term of protection is 20 years for all plants except trees and vines, which are considered more difficult to commercialise in a limited period.

More detailed information on this topic is available in *Module Seven: Plant Breeders' Rights*.

TRADE SECRETS

What is protected by trade secrets law?

Trade secrets are information of a business or technical nature that have commercial value and have been kept confidential. They can include secret processes, mixtures of ingredients, recipes, know-how or any other confidential information that may give a competitive edge or may otherwise be valuable. TRIPS requires that there be some form of legal mechanism available to stop the disclosure and unfair commercial use of information which:



- is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- has commercial value because it is secret; and
- has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Example – trade secrets protection for a food processing method

Say you have developed a new method for snap-freezing and thawing bananas so that they can be enjoyed fresh without discolouring and loss of texture. It may be an obvious application of an existing technology with some minor adjustments that cannot be patented (e.g. if a technology is already in use for another fruit such as the mango, and you make fairly obvious adjustments to it to make it work for bananas). Or you might decide the cost of patenting is too high and you believe you can commercialise your new method without revealing it to your competitors. But if you published an advertisement describing your method, or demonstrated your method to a group of banana farmers or potential investors, then you would not normally be able to stop other people from taking this method and using it for themselves, without any compensation or payment to you.

On the other hand, if you told your business partner or a potential investor about your new method, or demonstrated it to them, and this was done in strict confidence, so that they clearly knew they had an obligation to keep the information confidential, then the method could be protected by trade secrets law. You could even commercialise your method and use it for many years to process and distribute bananas, provided other people outside your business can't see how it works. There are several drawbacks. This form of protection depends on you taking the effort to keep the method secret. It also only extends to those to whom you disclose the method in secret. If someone else figures out how to use your method (e.g. by analysis or reverse engineering), and they developed their ideas independently of you, then they may make full commercial use of the method without owing you anything. What's more, if your method is still secret then the other person who independently came up with the idea may be able to get a patent.

Technology is often protected as a package of different rights. If your method for processing bananas was a significant technological breakthrough, then you might get a patent for the basic technology. But in using your method, you might develop further techniques for making it more cost effective, for instance in reducing the cost of refrigeration. These additional techniques may simply be know-how, not patentable in themselves, but could still be protectable as trade secrets.

From society's point of view, the patent system has been developed to encourage disclosure of inventions, so that there is an incentive to turn away from the kind of excessive use of trade secrets or confidentiality that might hamper the transfer of technology and the sharing of benefits from new technologies.

What material is protected by trade secrets law?

There are two general ways of protecting trade secrets, corresponding to the two main legal traditions – the common law tradition of the UK, the US and most Commonwealth countries, and the civil law tradition of continental European countries and those countries influenced by their legal systems. Under the common law approach, there is a general kind of legal action for breach of confidence – this gives you the right to take action against people who fail to honour an agreement with you to keep information in confidence – or who otherwise fail to live up to a relationship of trust relating to the information (for instance in exploiting the information for commercial benefit when it was only disclosed for preliminary evaluation). This form of legal action is part of the general background law within the common law tradition, and is not necessarily contained in specific legislation passed by the government. But many countries in the civil law tradition do have specific legislation, or statutes, that make it illegal to infringe trade secrets.

Trade secret protection or protection against breach of confidence is not limited to high-tech know-how. For instance, in Australia it has been used as a legal remedy against the unauthorized public disclosure of information, which was secret and sacred within the traditions of the Indigenous Pitjantjatjara people, when the disclosure was considered prejudicial to their culture and society.

How do you get legal protection for trade secrets?

TRIPS has a general requirement on governments to put in place some form of legal mechanism that enables action to be taken when trade secrets (or 'undisclosed information') are abused. But it leaves it up to national laws to determine how this happens. So countries use variations of the common law system, or have specific legislation, to define and protect trade secrets. Often, the protection of trade secrets is part of the general law against unfair commercial practices or unfair competition. These different systems do have common features. Generally, it is not necessary to register a trade secret to get protection for it (although it normally should be well documented). If someone later thinks of the same idea independently you have no rights against them and cannot stop them from using the idea. Also, if someone who has no connection with you can work out how your product was made simply by analyzing it ('reverse engineering'), then they are free to use that information to produce a competing product.

Trade secrets often constitute much of the valuable background knowledge that makes it possible to carry out a patented invention. It can, for instance, relate to a lot of the hard-won practical knowledge about fine-tuning a patented process to ensure that it operates most efficiently, and is better integrated with other manufacturing processes. It also relates to valuable commercial information, such as marketing plans and commercialisation strategies. So trade secrets or know-how often constitute a significant portion of the 'intellectual capital' that characterizes a successful enterprise.

Nonetheless, there is reluctance in some jurisdictions, especially common law countries, to recognize trade secrets or confidential information as a form of property in its own right, even though it can be sold and licensed. For example, the Canadian Supreme Court (*R v. Stewart*, 85 NR 171) concluded in 1988 that:

It appears that the protection afforded to confidential information in most civil cases arises more from an obligation of good faith or a fiduciary relationship than from a proprietary interest. No Canadian court so far has exclusively decided that confidential information is property, with all the civil consequences that such a finding would entail.

Generally speaking, reliance on trade secrets is less legally certain, more unpredictable a tool for managing technology, and less transparent for the public than the patent system.

The two different systems for trade secret protection

Hong Kong, China and the Republic of Korea are good examples of the contrasting approaches to protecting trade secrets. Hong Kong, China, described its common law legal system to the WTO TRIPS Council as follows:

Protection for undisclosed information is provided by the common law action for breach of confidence. The leading case is *Coco v Clark* [1969] RPC 41, where it was held that three elements had to be proved for a claim of breach of confidence to succeed: (i) that the information was of a confidential nature; (ii) that it was communicated in circumstances importing an obligation of confidence; and (iii) that there was an unauthorized use of the information.

Hong Kong courts have interpreted the second requirement as fulfilled not only where the originator of the information has communicated the information to the defendant in confidence, but also where a third party has come by the information, and it is considered that he must, from the nature of the information, have realized that he was not entitled to use it. (*Dr Lam Tai Hing v Dr Koo Chi Ling, Linda* [1993] 2 HKC 1).

An example of specific trade secrets legislation is the Republic of Korea's *Unfair Competition Prevention and Trade Secret Protection Act* which has this specific statutory definition of trade secrets:

Trade secrets shall mean production methods, marketing methods and other technical or management information useful for business activities which are not publicly known, have independent economic value, and have been maintained and managed as secrets through considerable efforts.

This law also specifically defines a wide range of activities as being in infringement of trade secrets, for instance acquiring trade secrets by theft, deception, coercion or other improper means, and provides for legal penalties

Who owns the rights in trade secrets?

Trade secrets are not protected as property at common law but the person whose secret has been disclosed or used can sue for breach of confidence. Statutory regimes provide that the owner of the trade secret is the person who developed the trade secret.

How long do trade secrets rights last?

Unlike patents and copyright, the term of protection for trade secrets is not limited. The legal protection of trade secrets can last indefinitely or until the 'trade secret' is made public. From society's point of view, trade secret protection can be less desirable than patenting, because by its very nature a patent requires the inventor to make available to the public a full explanation of how the invention works, so that understanding about the patented invention immediately passes into the public domain.

TRADE MARKS

What is a trade mark?

A trade mark is a sign used to distinguish goods or services in the market place from the goods or services of another trader. The trade mark can appear directly on the product (such as on a label on a bottle), in its packaging and other material (such as on a box or bag the product is sold in, and on instructions, guarantees and other documents), and in advertising and promotional material (for example, on a billboard or magazine advertisement). The actual shape of a container can be a trade mark – the shape of the famous COCA-COLA bottle is itself a trade mark in a number of countries. When a trade mark is used in the services sector (for example, banking, pathology services, internet or telecommunication services), the trade mark is used in association with the provision of services (on signs at an office or workshop, for instance, on documentation such as quotations, invoices and reports, or on a website offering or providing the service), and on promotion material (such as advertisements).



The main legal property of a trade mark is that it should effectively function as a sign that shows that a certain product is associated with one business in particular. How a trade mark works depends on the nature of the word or other sign in a particular sector of commerce. For example, the word APPLE is a distinctive trade mark for computer products in many countries – and it would be misleading for a non-APPLE computer or computer component to be sold under that trade mark, because a consumer would probably assume that a computer marked with that trade mark came from the well known computer company, or was somehow endorsed by that company for use in their computers. But in the food business – for example, for fruit juices or confectionery - the word 'Apple' is needed to describe a fruit and its flavour. A company could hardly sell 'Apple' fruit juice and claim that this was a distinctive trade mark. It would be

wrong to grant anyone exclusive rights to use the term. For this reason, the rights associated with a trade mark are linked to particular goods and services, and do not normally extend to other areas of commerce – it is not unusual for the same trade mark to be used by different businesses operating in completely different lines of business. For instance, “Prince” is a trade mark owned by at least two completely separate businesses, one producing sports equipment, the other providing information technology services.

TRIPS provides that any sign capable of distinguishing the goods or services of one undertaking (eg, an individual merchant, a company, or a cooperative) from those of others shall be capable of being a trade mark including personal names, letters, numerals, figurative elements and combinations of colours. Some countries extend the scope of the definition of trade mark, and allow for trade mark protection to cover distinctive sounds and smells, as well as the shape of the product itself or its container.

Example – trade mark protection for different products



The words TIGER BALM are registered as a trade mark in Australia for ‘Medicinal and medicated preparations for human use’ (registered trade mark 470186). The word ‘tiger’ is used in many other unrelated trade marks for other goods and services, so that the TIGER BALM trade mark would not create an unlimited right to prevent other businesses from using ‘tiger’ and images of tigers for other products. In the rather specialized field of medical preparations for tigers and veterinary medicine, the words ‘tiger balm’ may also need to be kept as a descriptive term for treatments that are specifically useful for treating tigers.

The word GARUDA is registered as a trade mark in Australia for a wide range of goods and services, including printed matter, games and playthings, model aircraft, travel insurance, money exchange, aircraft repair and maintenance, transport, travel arrangements, travel agent services, entertainment, cultural activities, training services, and provision of food and drink, accommodation (trade mark 821268), in the name of the well-known Indonesian airline company. But the same word, GARUDA, is also registered as a trade mark in relation to preserved, dried and cooked fruits and vegetables, and prepared nuts, in the name of a different company which may be unrelated (trade mark 711 937). The national emblem of Indonesia also includes an image of the garuda, which is a mythological bird in Indian and Indonesian culture. This may limit the use of particular images as trade marks, as it is an international standard that notified national emblems should not be used or registered as trade marks.

How do you get legal protection for a trade mark?

There are two distinct forms of protection. The most transparent and predictable way of protecting trade marks is through official registration at the national trade mark office – similar to registration of patents and PBRs. This is the preferred approach of most enterprises. But, unlike patents and PBRs, you do not have to register a trade mark for it to be protected by law. Rights to a trade mark can arise through use. In the example of snap-frozen bananas cited above, if you sold the bananas under the trade mark ‘Brilliant Bananas’ you would have the choice of trying to register ‘Brilliant’ as a trade mark in respect of fruit, or simply making use of the trade mark to build up a distinctive reputation in the market place over time, in the hope that you would be able to defend your interests if someone else tried to cash in on your reputation by representing their product as Brilliant Bananas.

What's the difference between registered and unregistered trade marks?

Both registered and unregistered trade marks are associated with the reputation of the trader in respect of specific goods and services. The signs ® and ™ are often used together with a trade mark. ® indicates that the trade mark is registered, and should only be used in connection with a registered mark. ™ indicates that the word or sign is presented as a trade mark rather than as a descriptive or other term, but it need not be registered – for example, you could sell your snap-frozen bananas as Brilliant Bananas™ to indicate that the term is being used as a trade mark. ™ can be used similarly for a 'service mark' – a trade mark used in respect of services.

Advantages of registered trade marks are that the protection dates from the application for registration and they can be easier and cheaper to enforce than unregistered marks. Also, registration may last indefinitely and the protection tends to be for a whole country not just a smaller area.

Advantages of unregistered trade marks are that there is no need to go through the registration process and no registration fees are payable. But it can be very difficult to enforce rights in an unregistered trade mark, as it's necessary to build up strong evidence that the public sees the word or symbol in question as a trade mark. Some marks are initially not registrable because they are not considered sufficiently distinctive. Clearly you couldn't claim as your trademark for your bananas 'Yellow Bananas' or 'Fresh Bananas' because these are descriptive terms that anyone should be free to use. In other cases, it is difficult to draw the line. For example, you might try to register 'Brilliant Bananas' as a trade mark, and this could be accepted because it is sufficiently distinctive, or it could be rejected on the basis that the word 'brilliant' should be available for any trader to use as a descriptive or laudatory term for the bananas they are trying to sell. Even if you failed to register the mark 'Brilliant Bananas,' this mark might nonetheless be important to the reputation of your business. Unregistered marks can be protected by unfair competition laws – if someone else uses an unregistered mark, this can be considered misleading or deceptive commercial conduct. In addition, if you used 'Brilliant Bananas' as a trade mark for several years, and you can prove that it has become distinctive in the fruit trade, then you might be able to register it subsequently on the basis that it has become distinctive through use.

What rights are associated with trade marks?

A registered trade mark right is infringed if a person uses in a particular commercial context a sign that is substantially identical to or deceptively similar to the trade mark for the promotion of similar goods and services to those protected by the trade mark. In essence, the trade mark registration can be used to prevent other people from using a similar sign on goods or services that suggests some form of connection with the owner of the registered trade mark. It generally can't be used to stop use of a similar trade mark in a completely different line of business (see the examples above). When a trade mark is considered 'well known' or 'famous,' the scope of the trade mark right is broader.

TRIPS provides for exceptions to trade mark rights such as fair use of descriptive terms if such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

How long do trade mark rights last?

TRIPS provides that initial registration and each renewal of registration of a trade mark shall be for a minimum of 7 years. The registration of a trade mark can be renewed indefinitely, and some trade mark registrations (such as 'Kodak') have been in force for well over a century. If a registered trade mark is not actually used or ceases to be used, then someone else may reasonably wish to use it. For this reason, a registered trade mark can generally be removed from the register after a certain delay if the trade mark owner has not used it or has stopped

using it. This is to ensure that unused or abandoned marks do not remain on the trade mark register when they conflict with other traders' legitimate interests. TRIPS provides that 'if use is required to maintain a registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner.'

Similarly if a trade mark becomes generic, that is it becomes commonly identified for a general purpose, then it may lose its distinguishing characteristic and cease to be a trade mark. For example Xerox was registered as a trade mark for electro-photographic copying machines and apparatus for fusing powder images in 1952, and was used widely for these kind of copying technology. This reached a point by the 1970s that the trade mark almost became a generic descriptive because many people referred to photocopiers and photocopying as xerox machines and xeroxing. Other trade marks such as 'Velcro' and 'Hoover' have similarly been in danger of losing their distinctiveness. Linoleum is now the standard descriptive English word for a form of flooring material originally made by coating canvas with oxidised linseed oil. This term was originally a trade mark in the name of the Linoleum Manufacturing Company (and linoleum flooring was also patented), but it is now a generic term which any manufacturer can use for their product.

INDUSTRIAL DESIGNS

The industrial design system protects the distinctive appearance of products – it only protects the look of items, and not how they function or the underlying technology. So if you had design protection for a new kind of folding chair, your rights would only extend to chairs that looked like your protected design, not chairs that folded in the same way.



Protection is given to distinctive ornamental or aesthetic elements of the product. To be eligible for protection, a design has to be new in appearance, although this can include relatively minor variations on existing designs. There is no need for the kind of 'inventive' or 'useful' qualities that apply for instance to patentable inventions. All that is required is that the design should differ in the way it looks from previous work in that area.

Under the TRIPS Agreement, protection has to be available for 'independently created industrial designs that are new or original,' and indicates that designs may not be 'new or original' if they 'do not significantly differ from known design features.' TRIPS also provides that protection need not be extended to designs which are purely dictated by 'technical or functional considerations.'

Designs can cover a very wide range of products, such as handicrafts, furniture, electrical appliances, food containers, textiles, clothing, toys and building materials. The industrial designs system is often very useful for middle-level innovators, including small or medium enterprises, which create innovative products that are not necessarily technological developments, but are nonetheless commercially valuable new products.

While not directly applicable to the products of biotechnology, design protection may be useful in product development in this field, as it can protect the distinctive appearance of products such as diagnostic kits and analytical tools. For example, Australian registered design AU 137103 S protects the features of shape and/or configuration of a 'point of care diagnostic device' produced by the Adeza Biomedical Corporation, and registered design AU 142947 S, held by the company Human GmbH, protects the appearance of a human midstream pregnancy test.

In the US, industrial designs are protected through design patents. Following is an example of a US design patent claiming 'the ornamental design for a device for chemical analysis of foods and other substances.' Along with the claim and other details of the individuals and company which created the design, there are eight drawings illustrating the design, one of which is reproduced here.



US000424457S

United States Patent [19] [11] **Patent Number: Des. 424,457**
Gordon et al. [45] **Date of Patent: May 9, 2000**

[54] **DEVICE FOR CHEMICAL ANALYSIS OF FOODS AND OTHER SUBSTANCES**
 [75] Inventors: **Virginia C. Gordon; Bennett W. Root, Jr.**, both of Huntington Beach, Calif.
 [73] Assignee: **Safety Associates, Inc.**, Tustin, Calif.
 [**] Term: **14 Years**
 [21] Appl. No.: **29/100,859**
 [22] Filed: **Apr. 22, 1999**
 [51] **LOC (7) Cl.** **10-04**
 [52] **U.S. CL.** **D10/81**
 [58] **Field of Search** D10/81; 435/7.92, 435/7.1; 435/318; 422/56, 58, 102; 210/238

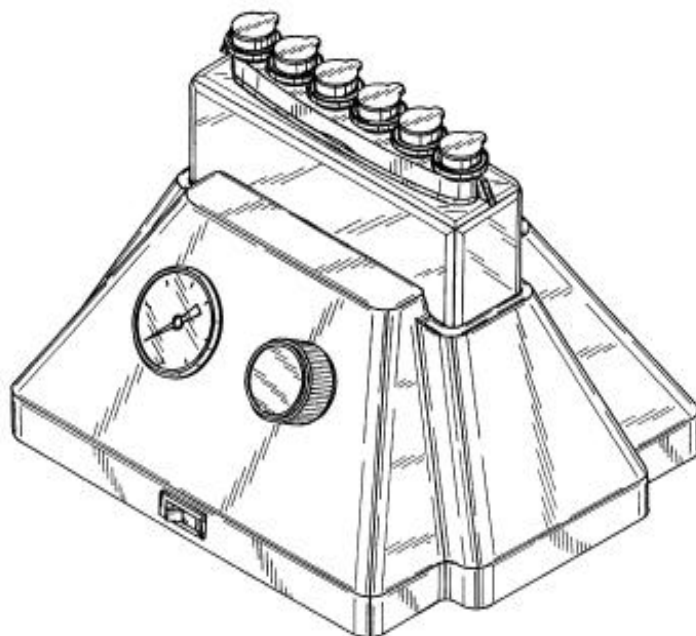
[56] **References Cited**
U.S. PATENT DOCUMENTS
 D. 282,399 1/1986 Stafford D10/81
 D. 333,630 3/1995 Marks D10/81
 5,958,704 9/1999 Stanzl et al. 435/7.1

Primary Examiner—Antoine Duval Davis
Attorney, Agent, or Firm—Robert D. Bayan; Stout, Uza, Bayan & Mullins, LLP

[57] **CLAIM**
 The ornamental design for a device for chemical analysis of foods and other substances, as shown and described.

DESCRIPTION
 FIG. 1 is a perspective view of a device embodying the design of the present invention.
 FIG. 2 is a front elevational view of the device of FIG. 1.
 FIG. 3 is a top plan view of the device of FIG. 1.
 FIG. 4 is a left side elevational view of the device of FIG. 1.
 FIG. 5 is a right side elevational view of the device of FIG. 1.
 FIG. 6 is a rear elevational view of the device of FIG. 1.
 FIG. 7 is a bottom plan view of the device of FIG. 1; and, FIG. 8 is an exploded perspective view of the device of FIG. 1.

1 Claim, 8 Drawing Sheets



COPYRIGHT AND RELATED RIGHTS

Copyright is concerned with the protection of original literary and artistic works – indeed, the French term for copyright is ‘droit d’auteur’ or ‘author’s right.’ But what constitutes a ‘literary or artistic work’ is very broad, and goes beyond creative works or aesthetic works like paintings, songs, or novels. The Berne Convention, which is the principal international agreement on copyright, provides that:

The expression “literary and artistic works” shall include every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression, such as books, pamphlets and other writings; lectures, addresses, sermons and other works of the same nature; dramatic or dramatico-musical works; choreographic works and entertainments in dumb show; musical compositions with or without words; cinematographic works to which are assimilated works expressed by a process analogous to cinematography; works of drawing, painting, architecture, sculpture, engraving and lithography; photographic works to which are assimilated works expressed by a process analogous to photography; works of applied art; illustrations, maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science.

TRIPS (and a later treaty, the WIPO Copyright Treaty) adds to this definition by specifying that computer programs (both in source or object code) shall be protected by copyright as literary works.

‘Related rights’ or ‘neighbouring rights’ describes a set of rights that are similar to copyright but do not directly involve rights to a work as such – these include the rights of performers (such as those singing or playing music), the rights of producers of sound recordings (separately from the musicians or songwriters), and the rights of broadcasting organisations. These rights are very important in some industries, but are of little relevance to the biotechnology field. However, copyright itself does have significant practical implications for researchers and commercial enterprises working with biotechnology.

Under copyright law, when you write a new article, a research report or a lecture, when you sketch a new diagram, or when you produce a computer software program, you automatically gain legal rights to stop others from reproducing or otherwise using this material – within reasonable limits.

If you write a commentary on recent developments in biotechnology and publish it in a journal or place it on a website, copyright gives you the right to stop other people from publishing it in another journal or placing it on their website without your permission. But copyright only covers the way you express your ideas, not the ideas themselves. TRIPS specifies that ‘copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.’ So someone else would be entitled to publish a similar commentary covering the same ideas as yours, provided it was not a copy of your own publication. And copyright is not absolute – for instance, it would not normally be necessary to get your permission for someone to quote passages from your commentary in the process of reporting on your views, or preparing material for educational purposes.

Copyright is different from patent protection and the other forms of IP discussed in this module in several important ways.

- It doesn’t need any formalities. There is no need to apply to a government office for copyright to be recognized. The legal right comes into being automatically when you produce the protected material. (But it’s a good idea in practice to apply the symbol ©, the name of the author, and the date of publication to notify people that copyright does apply to the material, unless you don’t mind if it’s copied or published without reference to you.)
- It only covers actual copies of the protected material, not just material that happens to be similar to it or coincidentally resembles it. So if you draw a diagram or take a photograph, and later someone independently produces material that is very similar to yours – which

you feel takes the essence of your original work – your copyright wouldn't apply to their work. There would have to be a process of copying or reproducing your actual work. By contrast, if you have a patent on an invention, and someone who has no knowledge of your research work later comes up with technology that takes the key elements of your invention, you can still use your patent to prevent them from commercializing their later invention. There is no need for you to prove that they have directly copied from you – you just have to show that they have used all the elements of the claimed invention in your patent.

Much of copyright law is about who can reproduce protected material, how much, and for what purposes. It also applies to other ways copyright material is used – for instance, adaptation, performance in public (for instance of a song or a play), translation (such as translating a textbook from German to Thai), and making it available to the public (like uploading it onto the internet). Exercising your rights in copyright works doesn't necessarily mean stopping others from using or distributing your copyright material. Some researchers, teachers, or commentators are pleased to see their copyright material widely reproduced and distributed without expecting direct payment for this. But they may wish to ensure that they are acknowledged as the author of the works, and that the material is not altered or used inappropriately. You can use copyright can be used to ensure that your work is reproduced and used in suitable ways, even if you do not want to use your copyright for commercial gain.

There are, in any case, limits on the degree to which you can exert your copyright. Most national copyright systems allow for limited forms of copying so that copyright is workable and doesn't become too much of a burden for society generally – these exceptions to copyright typically relate to educational, archival and private non-commercial use, as well as for reporting news, criticism, parody and other uses. These exceptions are often referred to as 'fair use' or 'fair dealing' of the copyright work.

Copyright for researchers

For researchers and academics, copyright has mainly been of concern because their work involves use of published works – textbooks, journal publications, research outcomes. If you have written a textbook, you may be concerned that unauthorized copies of the textbook become used so widely that there is no market left for the authentic copies of the textbook – apart from reducing your royalties from book sales, this may affect the viability of publishing an updated or revised edition of the textbook, for example. On the other hand, teachers and academics generally have an entitlement under copyright law to make photocopies or digital copies of some portions of a textbook or journal article for use in education. Copyright establishes the rules that apply to this sort of educational use of written material – generally, there's an attempt to balance the reasonable interests of the author or publisher with the public interest in having copyright material freely available for education, research, criticism and commentary. There is obviously a big difference between copying a few pages from a textbook and circulating them to your class for reference during a lecture or seminar, and making multiple copies of the complete textbook and selling them commercially. Copyright tries to draw the line between these two extremes.

Recent developments have broadened the scope of copyright that scientific researchers and academics need to deal with, including in the biotechnology field. For instance, computer software, both in source code (programming language) and object code (machine language) is now protected by copyright, as though it were a literary work. This applies to standard word processing packages, operating systems and spread sheets, for example, as well as specialist research and analytical software, so that making unauthorized copies of these programs for widespread distribution counts as a breach of copyright.

A second area where copyright can also be used to protect collections of data, such as a database of gene sequence listings – even if the individual data are not subject to copyright, copyright can protect the effort that is involved in compiling and assembling the data, provided this compilation amounts to a distinct work – in the words of TRIPS, compilations of data or other material are eligible for copyright material when ‘by reason of the selection or arrangement of their contents [they] constitute intellectual creations’ in their own right. In addition, there have been proposals for international recognition of distinct IP rights in databases, quite apart from copyright – the European Union has already recognized database protection at the regional and national level.

The effect of IP rights on databases (whether through copyright or distinct database protection) is still an area of some uncertainty, but it looks to become an increasing practical reality for people working in the biotechnology field, with the emergence of bioinformatics as a distinct field, and the growth of genomic databases.

1.3 Enforcing intellectual property rights

Intellectual property rights can be very valuable commercial rights for inventors, creators and researchers. As discussed above, IPRs are usually exclusive legal rights to do certain things in relation to an invention or creation. In order to ensure that IPRs serve their intended purpose, there must be a way of ensuring that legal action can be taken when they are infringed.

TRIPS requires WTO Members to provide effective enforcement remedies. It refers to ‘civil’ and ‘criminal’ remedies. In civil cases, the person owning the IP right files a complaint against the person alleged to be infringing that right. A court hears the two sides of the case, and makes a judgement as to whether the allegation of infringement is true or not. If the court decides that the complaint is correct, and there has been an infringement, then it can order various ‘remedies’ or ways of stopping the infringement and compensating for the damage caused by the infringement. Civil remedies include:

- injunctions (i.e. use of a court order to stop the use of an infringing product or process);
- damages (i.e. paying costs of infringement to the right holder);, and
- account of profits (i.e. payment of profits made by the infringer to the right holder).

Civil cases are the normal way of dealing with patent disputes. In the criminal system, the state itself deals with the infringement. Police can seize goods which are believed to be infringements, and the public prosecutor initiates a case against the person alleged to be guilty of the infringements. This procedure is rare for patent cases, and does not exist in most countries. Criminal enforcement of IPRs is more frequent for trade mark and copyright infringement, when this occurs on a commercial scale.

Another way to enforce IPRs is to use customs services at the borders of countries to seize infringing IP material before it enters the country. TRIPS requires that border enforcement measures be available for trade mark counterfeiting and copyright piracy.

For more information on enforcement of IP rights refer to *Module Nine: Licensing and Enforcement of Intellectual Property Rights*.

1.4 IP & the lifecycle of a new product

From a practical point of view, it is important to see IPRs in an holistic way – in other words, not to focus exclusively on one particular kind of IPR as being relevant to you, while ignoring other rights. To illustrate this, we look at how different IPR come to play in the lifecycle of an hypothetical new research program, project Lambda:

<p>RESEARCH PLANNING PHASE</p>	<ul style="list-style-type: none"> • A search of existing patent documents is undertaken, to: • Identify potential competitors • Determine the state of the art in existing research • Find niche opportunities • Avoid duplication of research efforts • Undertake market research • Examine investment and technology trends • Locate potential research or commercial partners
<p>RESEARCH PHASE</p>	<ul style="list-style-type: none"> • Confidentiality and the law of trade secrets becomes important to safeguard: <ul style="list-style-type: none"> ○ Research directions and outcomes of project Lambda ○ Agreements with research partners ○ Confidentiality within the enterprise or institution • Patent law considerations are also essential in relation to: <ul style="list-style-type: none"> ○ Publications by those working on Project Lambda ○ Participation in trade fairs and scientific conferences
<p>RESEARCH BREAKTHROUGH</p>	<ul style="list-style-type: none"> • Any outcomes must be kept confidential at least until patent applications are filed • A patent filing strategy needs to be adopted <ul style="list-style-type: none"> ○ Including a possible choice to keep the outcome as a trade secret and not pursue patents at all • Associated developments may be protected as industrial designs • Associated software and documentation might be protected through copyright
<p>DEVELOPMENT PHASE</p>	<ul style="list-style-type: none"> • An IPR licensing strategy is required • Trade marks may need to be developed • An international patent strategy is required, underpinned by a commercial strategy • Patents may be required on improvements to the original

	<p>breakthrough</p> <ul style="list-style-type: none"> • Cross-licensing or other ‘freedom to operate’ strategies to gain access to overlapping IP owned by others if needed to allow the product to be commercially developed and put on the market
MARKETING PHASE	<ul style="list-style-type: none"> • The marketing strategy will need to consider effective strategies for protecting and promoting trade marks and designs • It is necessary to monitoring the marketplace for possible infringement and enforcement action • The portfolio of registered patents, trade marks and designs will need careful management • There will be continuing issues of licensing and valuation of the IP assets from Project Lambda

1.5 Why Have Intellectual Property Rights?

The IP system raises complex policy issues, and there has long been a debate about the desirable scope of IP protection. This generally concerns the tension between the need to promote and reward innovation, creativity and productive private investment, and the need to ensure freedom of expression, the flow of information and cultural works, and access to technology. The debate over the desirability or otherwise of the various elements of IPRs has been extensive, and is beyond the scope of this Handbook. However, some general comments are provided to stimulate your further enquiry and reflection.

The objectives normally put forward for recognition and protection of IPRs are:

- To contribute to the development of national economies by assisting to:
 - encourage and reward innovation and development;
 - benefit from international trade opportunities; and
 - attract foreign investment and technology transfer
- To comply with international standards; and
- To recognise an inventor’s and creator’s right to be recognised and rewarded for their intellectual endeavours.

Contribute to the Development of National Economies

The main value of IP laws is that they contribute to the development of national economies. Countries have IP laws to:

- enhance trade and investment in their country
- encourage technological development
- develop internationally competitive enterprises
- assist the effective commercialisation of inventions and innovations
- promote social and cultural development, and

- secure international reputation for exports.

A national IP system does not guarantee automatic national prosperity and trade advantages. A patent does not in itself make an inventor rich, but skilful use of the patent system can be one path to commercial success. An inventor cannot normally get the rewards of an invention without a patent. In the same way, few nations can create sustainable industrial growth and international competitiveness without an effective, well administered IP system. Yet it is vital to bear in mind that IP rights are not given as privileges or favours – they are recognised and granted to promote the community interest. This also affects how they are administered and exploited – some legal systems have specific penalties for misuse of the exclusive rights provided under the IP system. Achieving the benefits expected of the IP system therefore requires a suitable system of checks and balances, something that can be very difficult to achieve in practice.

Encourage and Reward Innovation and Development

The grant of IPRs to creators and inventors is intended to encourage research, innovation and development for the benefit of the community. It is intended to help them to benefit from their invention by compensating them for the work put into developing their product or process. It also gives an incentive to make the investment to turn an invention into a product ready for the marketplace. It can be a long process, moving from the original flash of insight that led to the invention, to a finished product, available for the consumer, that has been tested and proven to be safe and practically useful.

This incentive works by protecting the right holders from ‘free riding’ by their competitors. A free rider benefits from the work of others without bearing the cost of making a creative work or invention. By limiting free riding, IP laws encourage investment of finance and research efforts into longer-term outcomes.

In principle, IP laws aim to benefit industry, businesses and the community. Industry can benefit financially from patent protection for their inventions that often need large investments of time and money to produce. The community benefits from the availability of more creations and inventions. Businesses can use trade marks to protect their reputation and name and designs protect the appearance of their goods in the marketplace. These protections are important to protect the investment that business makes in developing and marketing goods and services.

Benefit From International Trade Opportunities

Trade liberalisation has increased the pressure on domestic industries to become more competitive against international benchmarks – this entails access to new technologies, generation of indigenous technologies, and other strategies for producing higher-value products. Also, the relative value of raw commodities has been steadily dropping for many years. Products need to be more distinctive to benefit from international trade opportunities, drawing on inventiveness, quality, regional characteristics, and the application of specialist or traditional skills. Businesses need to build up and safeguard a distinctive presence and valuable reputation in global markets.

IP rights are part of the ‘added value’ in trade – the move towards producing more distinctive products, and away from trading in raw commodities. Patents can be particularly important to high technology inventions. But IPRs also represent added value to trade in many other goods and services, as they can safeguard a wide range of innovations, distinctive local qualities, designs, reputations, and traditions.

Example: Coconut Cream Soap



IP rights are not restricted to the high tech sector. Traditional products have been effectively protected by IPRs, although many opportunities have been lost. More effective use of the IP system can generate higher rewards for traditional or low technology products. For example, imagine a company in Fiji wishing to produce a new product based on an existing tradition of producing coconut cream soap. It could strengthen its position in global markets by:

- protecting trade secrets or confidential information associated with the know-how used in processing the coconut and producing the soap;
- taking out patents to protect any specific new processes developed to process coconut oil and to produce the soap;
- creating and protecting trade marks to give the soap a distinctive identity in global markets – for instance, the soap could bear the trade mark LUCINA;
- copyright to protect pictures and writing on the soap’s packaging and labeling and design protection for packaging and related accessories, for example drawing on Fijian traditional motifs;
- using certification marks to provide reassurance about particular qualities of the soap, for instance certifying the use of organic contents;
- geographical indications to strengthen the association in the minds of the consumer with the product’s origin – for example, from the island of Vanua Levu; and
- breeders may also develop a new strain of high-yielding coconut especially useful for oil extraction and soapmaking.

Instead of soap exported as a basic commodity, valued by its weight, these forms of IP potentially combine to create a valuable product, in this instance: ‘Lucina, Quality Fijian Coconut Cream Soap, made by the traditional methods of Vanua Levu, certified organic produce.’ The product could be sold in a distinctive package using traditional Fijian designs.

In addition to enhancing the value of inventions and other merchandise, IPRs themselves can be traded in global markets. For example, imagine that a Fijian company had patented an efficient new process to produce coconut soap. The patent owners could license rights to use that patented process in countries all over the world. The international licensing of the patent right is an example of how IP rights in goods can be traded in global markets quite separate from the trade in the physical product, which in this example is the soap.

Attract Foreign Investment and Transfer of Technology

The effectiveness and scope of IP protection is reported to be one factor in establishing the domestic infrastructure that attracts productive foreign investment including the transfer of new technology. TRIPS is seen in practice as the principal international benchmark for a sufficient IP system.

Example - Pharm-Biotech and “BanDolor” capsules

For example, imagine that a private company called Pharm-Biotech is deciding where to base a new research and manufacturing facility in the Asia Pacific region. The factory will manufacture Pharm-Biotech’s patented headache tablet called “BanDolor” and a range of other products. Pharm-Biotech intends to employ 100 local staff in its factory. Several countries are very keen to attract this foreign direct investment.

In developing an investment strategy, Pharm-Biotech is concerned to ensure that it can undertake the expensive steps of establishing a new manufacturing plant, undertaking extensive regulatory approval processes, training personnel (including passing on vital know-how and other skills) and investing in marketing, without the value of the investment being nullified by the emergence of copies of BanDolor. These copies could be poorly made, ineffectual or even toxic, with consequence negative impact on the future of the new product. Vital know-how may be unprotected, deterring transfer of this technology. The company’s decision will be affected by many factors – the nature of the domestic market, the overall global marketing strategy, relationships with suppliers and other commercial and research partners, infrastructure, and other matters such as the taxation and foreign investment regime. However, in an industry such as pharmaceuticals, which is heavily dependent on IP protection for return on investment, the nature of IP laws will be one factor in the decision to make the investment, and where to locate.

Meet international undertakings and resolve disputes

Membership of the World Trade Organization and implementation of the TRIPS Agreement is a pragmatic reason for countries to have IP laws – for many developing countries, this factor has influenced major changes to their IP systems in recent years. The ‘Uruguay Round’ was a series of multilateral trade negotiations under the auspices of the General Agreement on Tariffs and Trade (GATT) than ran from 1986 to 1994. This led to the signing of the WTO Agreement, which comprised a comprehensive package of agreements. These agreements covered a wide range of trade issues, including agriculture, trade in other goods, trade in services, and IP. They also established a common system for resolving trade disputes.

Membership of the WTO requires compliance with all the multilateral agreements under the WTO Agreement – it’s therefore not possible to join the WTO in the hope of benefits in other areas of trade and to avoid the obligations imposed by TRIPS. The TRIPS Agreement establishes a common standard for national IP systems, with some areas of flexibility and diversity. It also ensures that when two countries have a dispute about IP matters, the issue is resolved by an international process, in a transparent way according to agreed rules, rather than by leverage based on unrelated trade interests. Including IP rules, in the form of TRIPS, into the general WTO dispute settlement system has had some unexpected consequences – for instance, when Ecuador was denied effective access to the European market for its bananas, it was able to seek retaliation by proposing that it withdraw protection for certain forms of European-owned IP.

Recognise inventorship and creativity

Many of the reasons discussed above for intellectual property laws are economic reasons. Intellectual property laws contribute to the development of national economies in various ways. For example, intellectual property laws encourage and reward innovation and development, can lead to benefits from international trade opportunities, and can assist with attracting foreign investment and technology transfer.

Another justification for intellectual property laws is non-economic. That is, creators and inventors have a right to not only protect the results of their intellectual endeavours, but also to be recognised as the creators, or inventors, as such. This is why on a patent application the name or names of the inventors are required, even though the patent itself is owned by someone else, such as a university or corporation.

The costs of IP protection

In considering the operation and potential benefits of the IP system, it is important to bear in mind that the intellectual property also attracts criticism on several counts. These include concerns that IP protection can:

- create unjustifiable monopolies in the interests of large multinational companies;
- block access to new technology for developing countries;
- inhibit the flow and use of valuable information;
- force up the price of essential goods, such as pharmaceuticals, and making them effectively unobtainable;
- privilege western-style commercial and technological practices over those of other cultures and regions;
- set individual private rights over collective or community interests; and
- overrule ethical and environmental concerns.

On the other hand, others take the position that such criticisms overlook the positive possibilities of the IP system, fail to take account of the existing checks and balances available, or misrepresent the actual nature of IP rights. It is true that IPRs are rarely absolute or unlimited, and mechanisms for dealing with their abuse do exist. For example, the TRIPS Agreement recognizes:

- the need to ‘ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade;’
- the potential need for measures ‘to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology;’ and
- that some licensing practices or conditions pertaining to IPRs which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology

The debate over these issues is diverse and wide-ranging, well beyond the scope of this handbook. However, a common theme is the need for balance, transparency and mutual benefit, so that the IP system serves the broader public interest as well as providing sufficient private incentives for beneficial development and transfer of technology, fair commercial practices and creative endeavour. How to strike this balance is both a question of public policy settings, and a matter for skilled, effective use and administration of the IP system.

1.6 What is the International Framework for Intellectual Property?



IPRs are integral to international trade, and the way they are protected can also arise as an issue in international trade disputes. Administration of IP systems is also very difficult to manage without international cooperation.

It is important that there is a harmonised system of IP laws to facilitate international trade in this important and growing part of the economy. The international framework for IP rights plays a major role in harmonising the protection of these rights throughout the world. The administration of international IP issues is conducted largely by the World Intellectual Property Organisation (WIPO). The WTO (especially through the TRIPS Council) also plays an increasingly important role in such matters.

Several international agreements on IP rights, including the TRIPS Agreement and the UPOV Convention, have already been referred to above. The key set of international treaties for the IP protection of biotechnology inventions are the:

- Paris Convention for the Protection of Industrial Property (1883);
- Patent Cooperation Treaty (PCT) (1970);
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (the Budapest Treaty) (1977);
- Strasbourg Agreement Concerning the International Patent Classification (IPC) (1971);
- International Convention for the Protection of New Varieties of Plants (UPOV) (1961); and
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994).

Other international agreements that have IP implications for biotechnology include:

- the Convention on Biological Diversity (1992); and
- the Food and Agriculture Organisation (FAO) International Treaty on Plant Genetic Resources (adopted 2001).

Other important international treaties concerning other aspects of IP include the:

- Berne Convention for the Protection of Literary and Artistic Works (1886) (copyright, including software); and
- WIPO Copyright Convention (1996) (updating copyright rules for the digital environment).

WIPO and the WTO

The World Intellectual Property Organisation (WIPO) and the World Trade Organisation (WTO) are the two main international bodies that administer and oversee international intellectual property obligations.

WIPO is a specialised agency of the United Nations and is based in Geneva. WIPO administers most IP treaties, including the Paris Convention, the PCT, the Budapest Treaty, and the Strasbourg Agreement on the IPC. WIPO also provides wide-ranging technical assistance to Developing Countries through its development cooperation program.

The multilateral trade negotiations of the Uruguay Round, within the framework of the General Agreement on Tariffs and Trade (GATT), led to the signing of the WTO Agreement in Marrakesh in 1994. This agreement provided for the establishment of the WTO, which commenced operation in 1995. Among the bundle of integrated trade agreements administered by the WTO is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a specific agreement setting standards for national IP systems and providing for dispute settlement on IP issues. The WTO is an international organisation entirely distinct

from WIPO, although both organisations are based in Geneva. WIPO and the WTO have a cooperation agreement to manage their overlapping responsibilities for international IP.

Paris Convention for the Protection of Industrial Property

The Paris Convention (1883) was the first multilateral agreement for industrial property including patents, trademarks and designs. It provides that each country must grant the same industrial property protection to nationals of other parties to the convention as it grants to its own nationals - the principle of 'national treatment.' The Paris Convention also provides rules in relation to the right of priority for applicants who file first in a Member's country - this means that if you apply for a patent in your own country first, you can still apply in other countries within 12 months and the effective date of the foreign applications will be the same as your original application. This has enormous practical consequences for those working with patents. (A similar right applies to trade marks and industrial designs, although the period is only 6 months.) Among other things, the Paris Convention also provides that patents granted in different countries are independent of each other - in other words, if a patent is cancelled in one country, it is not automatically considered invalid anywhere else; and acceptance in one country doesn't create an obligation to accept it anywhere else.

The Paris Convention does not provide detailed rules about the legal tests that a patent must satisfy to be eligible for patent protection. Indeed none of the international agreements provide detailed rules about the substantive legal tests that a patent must satisfy - this is the province of legislatures, patent administration and courts at the national level.

Patent Cooperation Treaty (PCT)

Patents are still protected country-by-country (there are several regional systems, one covering most European countries, one covering Eurasian countries, and two operating in Africa). This means that getting patent rights in a number of countries can be highly expensive and administratively difficult. This is especially a problem for small and medium enterprises with limited resources. The PCT (1970) was developed to create a streamlined mechanism for applying for patent protection in many countries at the same time - it does not replace the national level, but it does reduce the initial administration and cost, and reduces the uncertainty about the benefit of proceeding with further investment. In essence, it allows the applicant to buy time while maintaining their entitlement to gain patent protection at a national level, so that they can assess the viability of the invention, get commercial backing, and check the likely success of the patent application. The key benefits of the PCT system are:

- It is possible to comply with a number of formalities in a centralized manner, rather than initiating the detailed paperwork needed for patent applications in many countries. This can significantly reduce the costs of applications.
- It allows you to maintain a legally recognized priority date and provides time to assess the feasibility of your patent before paying for expensive national patent applications in many countries. As previously noted, establishing your priority date is important in the patent process because it establishes the date from which novelty is determined and the date from which your right can be recognised if you are granted a patent.
- It provides for an international search. The results of this search are very valuable to the applicant. They allow the applicant to make more informed choices early in the patent process, and to amend the application to deal with any conflicting material, before the major expenses of the national phase of the patent process begin. The PCT system also provides for an optional international preliminary examination. As discussed in *Module Two* and *Module Three*, this examination does not have any direct legal effect, but gives the applicant a useful practical indication of potential difficulties that might be encountered at

the national level, so that suitable action (e.g. amendment, or withdrawal) can be taken when it is still relatively inexpensive to do so.

There is no such thing as a 'world patent'. The PCT process is perhaps the nearest thing there is to a global patent, but it does not result in anything but a modified form of patent application at the national level, and requires you to interact with the patent authorities responsible for any country where you want patent protection. The PCT simply provides a streamlined process for the patent application process in many countries at the same time. After the PCT international phase, applicants must comply with the patent laws in each of the countries in which patent protection is sought. The patent process is described in *Module Three: Reading a Biotechnology Patent and the Patent Process*.

Budapest Treaty - Deposit of Microorganisms

Patent law requires that details of an invention must be disclosed in a patent specification. The new technology must be described sufficiently to allow others in the community to put the technology into effect, for research and other purposes initially, and without constraint once the patent term expires. However, when an invention involves a micro-organism these two requirements are difficult to satisfy. First, it is very difficult for the patent applicant to describe in writing inventions relating to food and pharmaceutical products that involve after the patent term is finished it is very difficult for a person in the community to work an invention that refers to a microorganism unless they actually have access to it.

To overcome these kinds of problems, the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* (the Budapest Treaty) (1977) provides an easier way for patent applicants to satisfy the requirement for full description of biotechnology patents. The Budapest Treaty does this by providing for the deposit of a microorganism at a recognised "international depositary authority".

This procedure benefits patent applicants by saving them money. Members of the Budapest Treaty must recognise the deposit of a microorganism with any international depositary authority. This allows patent applicants to make one deposit with an international deposit authority rather than having to arrange deposits in each country in which patent protection is sought. The Budapest Treaty also sets up a mechanism to facilitate appropriate access to deposits.

Please see *Module Two: Biotechnology and Intellectual Property* for more details about patent law requirements.

Strasbourg Agreement Concerning the International Patent Classification

The Strasbourg Agreement Concerning the International Patent Classification (1971) sets up the International Patent Classification (IPC). The purpose of the IPC is to classify technology in a uniform way to make it easier to search patent documents using the IPC system of classification.

The IPC is used by patent offices in more than 80 countries and the secretariat of WIPO, which administers the PCT. According to WIPO, over the last 10 years IPC symbols have been put on over 1 000 000 patent documents.

A key part of the patent process is the searching of published documents to find out if an invention satisfies the legal tests for patenting such as novelty and inventive step. The search of published patent documents as part of the patent process is called a "prior art" search. Prior art, which includes search for novelty, is determined in accordance with prior publication in the field of technology that the claimed invention is for. Without a uniform system to classify patentable technology, such as that established by the IPC, searching for prior patent documents would be complex and unreliable.

The legal requirements for a patent are discussed in more detail in *Module Two: Biotechnology and Intellectual Property* and the practicalities of the IPC classification system are discussed in *Module Three* and *Module Four*.

International Convention for the Protection of New Varieties of Plants (UPOV)

The International Union for the Protection of New Plant Varieties (the UPOV Union) was established by the UPOV Convention, which was signed in 1961 and has since been revised three times. The acronym “UPOV” is from the French name of the organisation, which is *Union internationale pour la Protection des Obtentions Vegetales*.

The UPOV Convention sets out standards for national systems establishing rights for plant breeders who develop new plant varieties. For more information about plant breeders’ rights see *Module Seven: Plant Breeders’ Rights*.

UPOV provides for certain exclusionary plant breeders’ rights over the propagating material of a protected variety. These rights include rights over the production, reproduction, sale, export and import of propagating material for protected plant varieties. UPOV also provides for exceptions for acts done for non-commercial purposes, experimental purposes and acts done for the purpose of breeding other varieties, and optionally for farmers to save seed for their future plantings.

A new plant variety must be distinct, uniform and stable in order to be granted plant breeders’ rights.

The UPOV Union is supported by the Office of UPOV, which is headed by a Secretary-General. By agreement with WIPO, the Director General of WIPO is also the Secretary-General of the UPOV Union and UPOV is housed in the WIPO building in Geneva, although UPOV is a completely separate international organisation from WIPO, and has a separate secretariat. UPOV and WIPO work cooperatively together and UPOV shares its headquarters with WIPO in Geneva.

The only other international agreement that touches on plant breeder’s rights is the TRIPS Agreement. It provides only very general obligations in relation to the protection of plant varieties – it calls for use either of the patent system, or an effective separate (or *sui generis*) system, or both, to protect new plant varieties. The standards in the UPOV Convention are a widely recognized instance of this kind of *sui generis* system.

Agreement on Trade-Related Aspects of Intellectual Property Rights

The TRIPS Agreement is one of the major international IP treaties and is the only comprehensive international IP treaty. As noted above, TRIPS was one of the outcomes of the Uruguay Round of the GATT. It came into force on 1 January 1995. The TRIPS Agreement establishes the TRIPS Council, consisting of all WTO members, and is responsible for the administration of the TRIPS Agreement.

TRIPS builds on the existing IP standards in the WIPO Berne Convention for the Protection of Literary and Artistic Works (1886) and the Paris Convention (1883), and establishes international standards in the following areas of intellectual property.

Types of intellectual property covered by the TRIPS Agreement

- copyright and related rights
- trade marks
- geographical indications
- industrial designs
- patents
- layout designs of integrated circuits
- protection of undisclosed information
- new plant varieties

TRIPS also provides for remedies against anti-competitive abuse of each of these IP rights, such as coercive licensing practices.

The TRIPS Agreement is different from the WIPO treaties in two key ways. First, the TRIPS Agreement has detailed requirements for enforcement mechanisms in national legal systems (TRIPS Articles 41-61). Secondly, the WTO's Dispute Settlement Understanding provides an improved system for settling IP-related disputes between WTO Members. TRIPS was established to promote balanced systems for protecting the rights of creators and inventors, and to provide a more predictable, transparent and rules-based system that was available before to deal with international disputes over IP protection

Convention on Biological Diversity

The Convention on Biological Diversity (CBD) is an environmental treaty, which was opened for signature at the United Nations Conference on Environment and Development (the Rio Earth Summit) in 1992. The objectives of the CBD are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the use of genetic resources.

Although the CBD is an environmental treaty it is relevant to a consideration of IP issues. The CBD recognises that patents and IP rights may have an impact on the objectives of the CBD and calls on parties to cooperate to ensure that IP rights are "supportive of and do not run counter to its objectives". Further, the CBD requires that each contracting party

Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

This requirement has raised a number of issues concerning the protection of traditional knowledge and relationship between the CBD and TRIPS. Work is being done under the CBD to identify the ways in which IP rights impact on the objectives of the CBD. *Further Reading* pages and the *Annotated Bibliography* provides links to internet articles and websites where further research on this area can be done.

Treaty on Plant Genetic Resources for Food and Agriculture

The United Nations Food and Agriculture Organisation (FAO) recently concluded a treaty on plant genetic resources for food and agriculture, which has major significance for agricultural biotechnology, and the role of IP. It establishes a system of facilitated access to plant genetic resources that are held in public collections, with the aim of ensuring conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security.

Negotiations on the treaty highlighted issues concerning the balancing of the rights of IPR holders and the need for continued access to genetic resources and accessibility to protected varieties for food security. These raise issues of management and regulated use of IP rights, and the role of IP rights in relation to sharing the benefits from access to plant genetic resources for food and agriculture.

Biotechnology, Access to Genetic Resources & Traditional Knowledge

The CBD and FAO Undertaking mentioned above are just two elements of a broader international debate about the relationship between IP protection for biotechnology and such related matters as:

- ownership and control of genetic resources (such as plants and micro-organisms);
- recognition of traditional knowledge relating to plants and ecological systems (such as valuable knowledge about the healing qualities of plant extracts);
- incentives and benefits for conserving biological diversity (such as mechanisms for ensuring that local and Indigenous communities derive benefits from preserving the natural environment);
- prior informed consent for access to biological resources (such as legal requirements and mechanisms for ensuring that custodians or owners are properly involved and informed, and confirm their consent, prior to access to plant resources and related traditional knowledge in a protected area);
- equitable sharing of the benefits from research based on genetic resources and on related traditional knowledge (such as financial payments and royalties based on the commercialisation of products); and
- ethical and culturally based concerns about plant, animal and human biology (such as concerns that patent rights can in some cases cover life forms or life-processes).

This has led to claims, for example, that the CBD and the TRIPS Agreement are in conflict or tension because the CBD encourages collective ownership and management of genetic resources, while TRIPS provides for private rights (such as patent and plant variety rights) over innovations based on those resources. Others suggest that these two mechanisms can work effectively together, for instance if the patent system can be used to generate benefits that are shared with the custodians of genetic resources in exchange for access to those resources, for instance by creating contractual agreements. These are complex and contentious issues, and the various modules in this training package may provide insights into how they can be addressed.

Another international issue has been the interaction between IP rights and farmers' rights. In 1989, a resolution by the FAO defined 'farmers' rights' as 'rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in the centers of origin/diversity.'

Regional Agreements on Intellectual Property

In addition to the international intellectual property agreements discussed above, there are several regional agreements on IP that are particularly relevant to countries in the Asia-Pacific region. For example:

- the Association of South-East Asian Nations (ASEAN) has a Framework Agreement on IP, and

- the Asia-Pacific Economic Cooperation (APEC) has an Intellectual Property Rights Experts Group (IPEG) that promotes intellectual property rights.

APEC IPEG initiatives

The APEC IPEG provides practical support for APEC-wide implementation of TRIPS. It promotes a more efficient and harmonised administration and enforcement of intellectual property rights backed by greater public awareness and more skilled use of the intellectual property system in the business and public sectors. IPEG also promotes policy dialogue and exchanges of information on emerging issues.

APEC-IPEG members comprise Australia, Brunei Darussalam, Canada, Chile, Chinese Taipei, Hong Kong, China, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, People's Republic of China, Peru, Republic of the Philippines, Russia, Singapore, Thailand, United States and Vietnam.

ASEAN Framework Agreement

The ASEAN Framework Agreement on intellectual property promotes wide-ranging intellectual property objectives. It promotes:

- the strengthening of civil and administrative procedures and remedies for infringement of intellectual property rights
- the provision of technical cooperation for the implementation of TRIPS in relation to patent search and examination, computerisation and human resources development;
- compliance of TRIPS-consistent intellectual property laws;
- the implementation of an ASEAN Regional Trademark and Patent Filing System;
- the implementation of an ASEAN Common form for Trade Mark and Patent applications; and
- the public awareness of intellectual property in the public and private sectors.

ASEAN members comprise Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam.

1.7 Summary - Module One

What is intellectual property?

Intellectual property is a system of limited legal rights granted to reward inventive and creative endeavours, and to limit commercial free-riding. Some types of intellectual property rights relevant to biotechnology are:

- patents for new inventions
- plant breeders' rights for new plant varieties
- protection for new industrial designs
- trade secrets for technical business or commercial information
- trade marks for distinguishing marks of products or services.

Why do we have intellectual property rights?

Intellectual property rights can benefit individual researchers, industry, national economies and the community. Some objectives for the grant of intellectual property rights are to:

- reward inventors for their inventive endeavours
- encourage research and innovation for the benefit of the community
- assist inventors and industry to effectively commercialise their inventions and innovations
- assist the development of national economies by encouraging and rewarding innovation, and facilitating access to benefits from international trade opportunities
- attract foreign investment and technology transfer
- comply with international standards
- recognise an inventor's right to benefit from their invention.

What is the international framework for intellectual property rights?

The international framework for intellectual property rights and biotechnology includes:

- the WTO TRIPS Agreement, which covers patents, plant breeders' rights, trade secrets, trade marks, copyright, designs and integrated circuits, and enforcement and dispute settlement.
- the Paris Convention for the Protection of Industrial Property, which provides rules on patents, trade marks, designs and unfair competition
- the Patent Cooperation Treaty (PCT), which provides a streamlined process for making an international patent application with the effect or reserving rights in many countries at once
- the Budapest Treaty for the Deposit of Microorganisms, which provides an easy way for patent applicants to refer to a microorganism in the description of their invention
- the Strasbourg Agreement Concerning the International Patent Classification (IPC), which sets up the IPC system of technological classifications, facilitating patent searching
- the International Convention for the Protection of New Varieties of Plants (UPOV), which provides international standards in relation to the protection of new varieties of plants
- other agreements that are primarily environmental but have implications for intellectual property such as the Convention on Biological Diversity (CBD) and the Food and Agriculture Organisation (FAO) International Treaty on Plant Genetic Resources.

1.8 Group exercises - Module One

Module One sets out an introduction to intellectual property law. Please discuss Module One with your fellow participants and prepare answers to the following questions. You could either use the questions as a basis for general discussion, or prepare individual answers to the questions.

Exercise 1.1 - comparison of different types of intellectual property

Please review the material in this Module on:

- Patents
- Trade secrets (confidential or undisclosed information)
- Plant breeders' rights
- Trade marks

and refer to the relevant sections in the TRIPS Agreement in *Annex One*. Prepare a comparative table based on the following format, and answer the questions for each IP right, writing down the relevant TRIPS Article(s) where appropriate.

	Patents	Trade secrets confidential information	Plant breeders' rights	Trade marks
What kind of material is eligible to be protected by this right?				
What kind of limitations, restrictions or exceptions to this right are available?				
What do you need to do to get this right?				
Is there a limited term of protection? If yes, what is it?				
Give practical examples of how this right could be (i) a useful benefit, or (ii) an impediment to a business or other enterprise in your country.				

Exercise 1.2 - different types of intellectual property can exist in one product

You and your university research colleagues have invented eye drops that soothe sore, itchy and red eyes affected by air pollution. You used a new production method to develop the eye drops. In doing so, you have created a new shape of dispenser which could also be used as a distinctive bottle for the eye drops – it looks strikingly new, but also functions in a new way that makes it easier to use for patients treating their own eyes. You have also found that adding a particular mixture of natural products to the eye drops improves their effect. You want to market your invention with the trade mark “Cee Clear” and a logo consisting of a stylised ‘C and eye’ design. You are also applying to receive the official certification of this product by the semi-government Eye Care Council in your country.



CeeClear

What kinds of intellectual property rights could you use for your product?

What sort of issues would you need to address in gaining those rights?

Who would own the rights – you and your colleagues, the university, or a separate company?
What approach would be best:

- in ensuring the product was commercially successful?
- in ensuring that your university was able to fund future research?

Exercise 1.3 - Benefits of international intellectual property treaties

There are many international treaties that have contributed to a harmonized international framework for intellectual property protection – the TRIPS Agreement is one of many, and TRIPS is itself based on other treaties that were negotiated over many years. The harmonised intellectual property system includes common basic legal standards, similar administrative processes (or directly integrated administration), and common standards for such matters as classification and publication.

What are the potential benefits and the potential problems of an internationally harmonised IP system?

Exercise 1.4 - Benefits of intellectual property to your country

How can intellectual property rights benefit you and your country? What costs and potential disadvantages are there? TRIPS suggests that the IP system should

- contribute to the promotion of technological innovation and to the transfer and dissemination of technology,
- to the mutual advantage of producers and users of technological knowledge
- and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

How do you think these objectives for the IP system could best be achieved in your country?
How can these objectives be achieved in the work of your own organisation or institution?