



**FOREIGN
AFFAIRS AND
TRADE**



the Australian Government's overseas aid program

Module Ten

Case Studies on Commercialising Research

**Intellectual Property and Biotechnology
A Training Handbook**

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10.1 Objectives for Module Ten

By the end of this Module you should have an understanding of:

- Approaches to collective discussion of the trend towards commercialisation of research conducted by public institutions, including through conducting practical workshops
- Some issues that arise in taking a biotechnology invention to market, including practical experience from the hypothetical “Papayas” case study in:
 - identifying the relevant issues before commercialisation of an invention
 - analysing these issues, and
 - deciding whether to market an invention
- The steps taken to commercialise research in the Bt cotton case study including how Monsanto (the patent owner):
 - developed the Bt gene
 - collaborated with CSIRO to create new cotton varieties using the Bt gene
 - obtained the necessary regulatory approvals, and
 - licensed the use of the Bt technology through a technology users’ agreement

10.2 Workshop on IP management for researchers

Training in IP management

The focus of this Module is on group training in the management of IP rights. It describes two case studies, one hypothetical (Eternal papayas) and one an actual product (Bt cotton). These are designed to be used to promote group discussion of the various approaches that can be taken in commercialising biotechnology research, and the sort of considerations that need to be taken into account. Before developing these specific case studies, this Module discusses another approach to training in the management of IP rights: holding a workshop or training seminar, using the comparative expertise and practical knowledge of a few researchers who have been involved in developing research outcomes for the public, either through the commercial market or by other means.

Making effective use of the IP system to support research involves a complex set of new skills and careful program management. Unlike the technical aspects of patent law, for example, this is an inherently practical matter that cannot be reduced to a well-defined set of principles. While there are general guidelines, how those guidelines are applied in such a way as to stimulate and support research is a more important issue.

There is no substitute for direct experience in the field, including through sharing experiences of successes and failures in bringing new biotechnology to the market place. A workshop or training seminar is one useful approach to developing the necessary awareness and skills, if a number of individuals are available with suitable backgrounds in research and commercial environments – ideally, there should be a mix of personnel, from public research institutes, private technology companies, universities, and technology brokers or venture capitalists.

To illustrate this approach, this part of Module Ten describes a recent APEC workshop which drew together researchers from several newly-commercialising research institutes and researchers and IP policy officials from a range of developing countries. These were public sector research institutes with a continuing public focus, and a research organisation that had recently become a public company.

Workshop objectives

The objectives of the workshop were:

- To consolidate the topics covered in technical training on IP law and practice;
- To highlight areas of practical concern for research and technology management; and
- To exchange and compare experiences in the use of the IP system by research institutes, with a view to developing practical guidelines involving representatives of research institutes.

The participants who led the discussion were asked to draw on their own experience in discussing these questions:

- What have been the strategic IP considerations in your research and development programs?
- What were your IP success stories – what were the elements of success?
- What have been the failures – inventions that were not effectively protected by IP and were taken up successfully by others, or inventions that weren't put onto the market because of IP management issues?
- Is it inevitable in a research program to have a mix of IP successes and failures?
- Has lack of awareness or limited IP-related skills led to lost opportunities?

- What are the knowledge gaps and training needs? Do researchers, research managers, technology managers and government officials concerned with technology issues need specialized IP training? What kind of training programs have been successful?
- Does the pressure to commercialise and to secure IPRs change research priorities and direction?
- How can a research institute balance its policy interest in producing beneficial new technologies with a patenting and licensing program? What strategies can be used to disseminate new technology to the public?
- What ethical and cultural issues have arisen in developing and commercialising biotechnology? How have these been addressed?
- How can managers promote an innovation culture, and balance scientists' interest in exchanging ideas and publishing their research, with a confidentiality regime to protect new IPR?
- Is there a danger of pursuing a patent as an end in itself, rather than as part of an overall research and commercialization strategy?
- Have IPRs been used effectively to secure funding and the enabling environment for further public-interest research?
- What models have been effective for partnerships between research and business interests in financing, planning and commercializing research in the biotechnology field? What do these models tell us about who should own individual IPRs, and how they should be licensed, financed and enforced?
- How have patent information resources relating to biotechnology been used:
 - in planning research and looking for new research opportunities?
 - to secure freedom to operate in research programs?
 - in identifying potential research and investment partners?
 - to gain access to new technologies, through licensing or cross-licensing?
 - to monitor technological developments?

Discussion of the issues

In one example, concerning the development of a vaccine, the market leaders including major pharmaceutical companies were concentrating on identifying genetic structure, while a much smaller company was able to patent important methods. This led to a valuable partnership and a joint program to develop a vaccine, with a substantial royalty stream going to the smaller company. The key message to researchers was that if you have a valuable piece of the big pharmaceutical companies' puzzle, and you have intellectual property rights over it, then you can be in a strong bargaining position.

A second example raised the question of researchers' independence. A small company in association with a university explored a link between a virus and a form of cancer. A relatively small research budget was greatly eclipsed by the resources of the major companies. Research into this link produced patent rights, which were successfully licensed to a major pharmaceutical company. The question was raised as to whether private companies had the luxury to engage in original research involving linkages that do not appear to have a direct commercial application. The pressure to justify research as commercially viable could limit research directions. The effect

of this was to introduce an additional step into research planning – originally, the question was whether the project was scientifically sound and technologically viable; now there was an additional consideration – could the project have IP potential and could it generate income. For scientists, this change of focus had significant ramifications.

- It could limit the scope of research.
- It was necessary to keep effective and accurate laboratory notebooks, which could be a difficult cultural change for researchers.
- It called for precise timeframes on the part of scientists who may not be effective at managing their time.
- It meant that scientists had to curb their impulse towards publishing and sharing information on research developments, and had to take a more cautious approach at least in the initial phases of research.

A third example concerned a not-for-profit research institute. This had only recently developed a focus on IP. This was because:

- changed economic conditions meant that funds available from private charitable trusts were reduced and no longer sufficient to support research; and
- clinical trials to prove the safety and efficacy of new treatments, and to achieve regulatory approval, were extremely expensive; it had proven impossible to obtain financial backing to bring a new product onto the market without IP protection.

This meant that it was actually not possible to make the benefits of health research available to the public without a commercial partner and a program of IP management. Some of the considerations that had to be taken into account when introducing an IP program were:

- Equally important as patenting were material transfer agreements, confidentiality agreements, research and collaborative agreements.
- Collaborating scientists had to be prepared to discuss financial arrangements early, to ensure that there is a clear understanding from the beginning.
- Patenting should be done as soon as possible – this also helps to meet the scientists' interest in publishing their work at an early stage; at the same time, the patenting program should take into account possible technological changes that might yield broader applications for the invention.
- Not all researchers needed to have detailed training on IP – overdoing it could be counterproductive – but all needed to have a general understanding of IP principles and processes.
- The commercial aspects shouldn't be overemphasized – it remained fundamentally important for the research program that scientists should be able to exchange ideas and have the freedom to maintain their creativity.
- To capture all IP generated by an institute, a system could be established to scan all abstracts before they are submitted to journals for publication; this could be linked to a patent committee which would make strategic decisions about patenting.

Overall, those managing research institute should consider how to improve the use of the patent system without preventing or deterring researchers from continuing basic research. To the contrary, effective use of the IP system can be used to sow the seeds for future research, and to help direct research towards successful outcomes, without needlessly repeating work done elsewhere.

Your workshop

You may wish to conduct similar workshops to facilitate training in this area. There is no one solution to the challenges of blending research with commercialisation, but a discussion of the practicalities of IPR management and the solutions applied by others may assist you and your colleagues to work out your own solutions. The following case studies are provided to assist such group discussions – for example, you could consider how your own institute, working within your own country’s legal and commercial environment, would tackle these case studies, and use this as a springboard for general discussion about IPR management..

10.3 Group Exercise on Eternal® Papayas

This case study is about the hypothetical invention of transgenic Eternal® papayas within a fictional research institution. It will give you a chance to consider what practical steps you might need to take before commercialising an invention, focussing on how to get “freedom to operate” – in other words, to work out whether you can commercialise a new technology without running into problems with intellectual property rights that others might hold.

The Commercialisation Checklist for Eternal® Papayas

✓ **Develop a combined R&D and IP strategy**

The South East Asian Institute of Biotechnology requires all researchers to develop a combined research and development and intellectual property strategy, with a focus on working with local commercial partners to promote the availability of research outcomes for the benefit of local producers. Agus, a scientist with the Institute, prepared such a strategy before starting research in to papayas. The strategy aimed at getting useful IP rights and ensuring he could commercialise any invention if his research turned out to be successful.

The IP strategy involved aiming at a mix of patents and plant variety rights, and trade mark protection, and required research into different approaches to allowable subject matter for patents in different markets, particularly the differences on patenting plant inventions.

✓ **Do a patent survey**

With the assistance of professional patent searchers, Agus undertook extensive searches of patent databases to see what research had already been done that is relevant to his project, to work out what other researchers and institutions were doing work that might be useful for him, and to check for existing patent rights that could interfere with his proposed research techniques and the development of his research outcomes. This helped focus his research planning to ensure that he didn’t repeat earlier research, he could approach potential research collaborators and commercial backers, and he knew in advance about potential problems with existing patent rights. He also surveyed relevant plant variety rights, because these might also be relevant to his work on papayas.

✓ **Create a new invention**

After many years of research Agus developed the Eternal® papaya which has an exceptionally long shelf-life, so that it can be enjoyed fresh after being stored and transported for long periods. This saves cost in freighting papayas to export markets.

✓ **Protect confidentiality until patents are applied for**

Part of Agus’s R&D and IP strategy was to keep his invention in confidence until a patent application had been made. This helped the Institute get patent protection for Eternal® papayas

in Indonesia, Malaysia, Australia, Europe and the US. Agus's lab notebooks helped to prove he was the first to invent Eternal® papayas, in case it was necessary to defend patent rights in the US.

✓ **Keep track of costs**

Agus and the Institute kept a record of all the costs of developing Eternal® papayas, including the costs of getting advice from a patent attorney and commercial adviser. They knew that this would be useful in their dealings with their commercial partners and in ensuring the process would contribute to the future work of the Institute.

✓ **Do business research before commercialisation**

As the patent owner, the Institute developed a business strategy, which set out goals and included a budget. It researched demand for the invention and decided to market the invention in the countries in which Eternal® papayas is patented. It also hired a consultant to investigate the health and safety regulatory approvals would be needed before Eternal® papayas could be sold, and developed a plan for financing these approval procedures by involving a commercial partner.

✓ **Decide which model of commercialisation is best for you**

The Institute did not have the money or the business skills to market Eternal® papayas by itself. So, it licensed a company called "PT Biovarietas" to market the invention in return for royalties, which would be shared with Agus because he was the inventor.

✓ **Establish freedom to operate**

There is still one important consideration to take before Eternal® papayas can be fully developed and commercialised. The Institute needs to ensure that PT Biovarietas will have "freedom to operate". That is, it needs to check whether marketing the invention will infringe the rights of any other people (called "third parties"), and deal with the legal or technical implications of any third party rights. In the exercises below you will work out if there is freedom to operate to market Eternal® papayas.

The Steps to Ensure Freedom to Operate for Eternal® Papayas

This exercise focusses on assessing whether the Institute, and its commercial partner, PT Biovarietas, have freedom to operate in putting Eternal® papayas onto the market. More details about 'freedom to operate' are in *Module Eight: Researching and Intellectual Property*.

The technologies used in Eternal® papayas

- Agrobacterium-mediated transformation
- Binary Vector System to move constructs into plants
- Chimaeric gene constructs: trait / selection including:
 - CaMV 35S promoter
 - nos promoter region
 - ACC synthase coding region
 - nptII coding region
 - 3' ocs terminator region
 - 3' nos terminator region
- Down-regulation using co-suppression

The proposal for commercialisation of Eternal® papayas

The Institute knows that PT Biovarietas proposes that the transformation will be carried out locally in Indonesia. The plants also will be regenerated and grown locally. Some fruit will be consumed locally and the remainder will be exported.

As noted above, the target markets for Eternal® papayas include Malaysia, Singapore, Australia, Europe and the US. The Institute proposes that exports will start in 2007 to Malaysia, Singapore and Australia, then in 2009 to Japan, Europe and the US.

Exercise 10.3.1 - identify the technologies used in Eternal® papayas

The first step in working out whether the Institute has freedom to operate is to list all the technologies used in Eternal® papayas. What are all the technologies used in Eternal® papayas (see the list that is set out above)?

Exercise 10.3.2 - identify the relevant existing patents for Eternal® papayas

Secondly, the Institute needs to carry out patent searches to identify all the potentially relevant patent specifications for the Eternal® papayas technology. Potentially relevant patents are patents on any of the technologies used in Eternal® papayas. The Institute needs to get copies of the specifications and claims. For this exercise, the patents in potentially relevant technologies are summarised in Attachment 1 and the relevant claims are at Attachment 2.

Exercise 10.3.3 - interpret the scope of existing third party patents

The third step is to interpret the scope of the claims of the relevant existing patents and decide whether commercialising Eternal® papayas would infringe the rights of third parties. You need to work out whether the Institute needs a licence from anyone to commercialise Eternal® papayas. Remember to check the term of the grant of patent. The patent term might be finished or it might be nearly finished. You will need to look at the table at Attachment 1 to see the potentially relevant patent specifications filed. You will also need to analyse the claims in these patents that are at Attachment 2.

- (i) Can Eternal® papayas be exported to Malaysia? Why? Are any third party licences needed? From whom?
- (ii) Can Eternal® papayas be exported to Australia? Why? Are any third party licences needed? From whom?
- (iii) Can Eternal® papayas be exported to the US? Why? Are any third party licences needed? From whom?
- (iii) Can Eternal® papayas be exported to the EU? Why? Are any third party licences needed? From whom?

10.4 Case study: The commercialisation of Bt Cotton

Cotton containing the Bt gene – known as ‘Bt cotton’ - was among the first genetically modified crops in widespread commercial production. This case study sets out the approach taken by the multinational company Monsanto to commercialise Bt cotton in Australia, through various legal agreements with owners of other intellectual property rights. Bt cotton has been commercialised in Australia under the trade mark INGARD® and in many other countries under the trade mark BOLLGARD®.

Cotton production is one of Australia’s biggest agricultural industries, contributing around \$900 million a year in export income. INGARD cotton was the first genetically modified crop approved for commercial release in Australia. Monsanto, which held a patent on the Bt gene, developed a unique commercialisation strategy to get a viable financial return on its R&D expenditure in the seed market.

This case study considers:

- the nature of INGARD cotton;
- the kind of intellectual property protection applicable to Bt cotton;
- the health and safety regulatory issues faced by Monsanto in commercialising the Bt gene;
- the key players with whom Monsanto joined to commercialise the Bt gene in cotton, and
- the relationships that Monsanto developed with those key players in order to commercialise the Bt gene.

What is INGARD Cotton?

Cotton is naturally vulnerable to pests such as the cotton bollworm (*Helicoverpa armigera*) and the native budworm (*Helicoverpa punctigera*), commonly called heliothis pests. Managing these pests is a major problem for many cotton farmers. The bacterium *Bacillus thuringiensis* naturally produces a protein (Bt) which is toxic to these pest, and is itself used as a pesticide in organic farming.

INGARD cotton has been modified by the insertion of the Bt gene derived from *Bacillus thuringiensis* together with a promoter region into the cotton DNA. The genetically modified cotton plant expresses the Bt toxin. When these caterpillars eat the leaves of the modified cotton plant, the protein interrupts their digestion which causes them to stop feeding and die. The impact of the gene is very specific. It kills only the particular pest species and has no impact on natural predators such as spiders. It is also harmless to humans and other animals.

KEY DATES IN THE DEVELOPMENT OF THE INGARD BT TECHNOLOGY

1901: Humans first “discovered” Bt when Japanese bacteriologist Ishiwata Shigetane isolated some on a diseased silkworm, *Bombyx mori*, in Japan. Shigetane called Bt the *Sotto bacillus*, but this name did not last.

1915: German scientist Ernst Berliner isolated Bt from a dead Mediterranean flour moth, *Angasta kuehniella*, that he found in a grain mill in the German district of Thuringen. He named it, *Bacillus thuringiensis*. Berliner’s name did last.

1927: The first Bt preparation targeting Lepidopteran insects was introduced in Germany. It was based on a Bt called *kurstaki*, sometimes called *berliner* after the scientist who named Bt.

1938: The first commercial Bt product, called Sporeine, was released in France.

1940s: With World War II came a surge in chemical advances, such as antibiotics and insecticides. Cheap and effective chemicals helped farmers solve many formerly unsolvable problems.

1957: The first large-scale Bt-based produce was sold by Sandoz Corporation. It was marketed as Thuricide, and was based on Bt *kurstaki*.

1966: USDA scientist Howard Dulmage jump-started the US Bt industry by isolating a more effective strain of Bt *kurstaki*. Named after Dulmage, “HD-a” quickly became the basis for many new Bt commercial products. It still is.

1977: Two scientists reported that, for the first time, a Bt variety, called *israelensis*, isolated in 1976, killed mosquito and black fly larvae; both are from the order Diptera (two-winged insects – mosquitoes and flies). This was the first documented case of a Bt strain killing an insect other than a caterpillar.

1981: Scientists Ernst Schnepf and Helen Whiteley were the first to clone (make an identical copy of) a Bt toxin gene. Soon after, these scientists sequenced (or chemically spelt out) that same gene. By 1989, more than 40 Bt genes were sequenced.

1985: Global sales of Bt insecticides exceeded \$50 million, but remained less than 1% of the insecticide market.

1987: Three groups of scientists spliced Bt genes into cotton plants. None of the plants was commercially viable, but a brand new way to deliver Bt was created.

1988: A Monsanto scientist produced the first cotton plants with Bt toxin genes expressing their protein at potentially commercially viable levels.

1990: With United States Department of Agriculture approval, Monsanto began field tests of Bt cotton in the USA.

1992: With approval from the Genetic Manipulation Advisory Committee, field trials commenced in Australia.

1996: Approval for use in limited areas in Australia.

The application by Monsanto for commercialisation of INGARD cotton in Australia summarised the nature and effect of the genetic modification as follows:

“The parent organism is cultivated cotton, *Gossypium hirsutum*. Cotton, which is exotic to Australia, is grown in Australia as a major agricultural crop. The transgenic plants have been modified to express a gene, derived from the bacterium *Bacillus thuringiensis*, that produces a highly specific insecticidal protein (Bt) that is toxic to the major caterpillar pests of cotton. Caterpillars are normally controlled by heavy spraying with pesticides. The Bt protein is non-toxic to humans, other animals and most other insects.

“A delta-endotoxin gene has been inserted into the cotton to produce the CryIA(c) insecticidal protein. Transgenic plants express this gene in most plant parts, particularly in young leaves and flower buds. When the plants are attacked by insect pests which are susceptible to the toxins, the toxins initially inhibit insect feeding and subsequently result in the death of the insect pests. The target pests are two species of *Helicoverpa*, major pests in the cotton industry. In addition to the Bt-toxin genes, the transgenic cotton plants contain a selectable 'marker' gene, neomycin phosphotransferase, that confers resistance to the antibiotics kanamycin and neomycin.

“This marker gene was inserted to allow selection of the transgenic plants from non-modified plants during regeneration of the plants in tissue culture. The inserted DNA also contains a bacterial gene, encoding resistance to spectinomycin and streptomycin, which is not expressed in the transgenic

plants. This gene was used as a selectable marker for the genetic manipulations in the bacterial hosts, before the transfer of the gene to the cotton plants.”

What IP Protection applies to INGARD cotton?

Three types of intellectual property have been used to protect INGARD® cotton:

- the Bt gene is protected by a patent
- the name INGARD is protected by a trade mark registration, and
- some new cotton varieties that use the Bt gene are protected by plant breeders’ rights.

Each of these types of intellectual property is discussed below.

Patent protection for the Bt gene

Patents provide legal protection for inventions, including products or processes, that are new, involve an inventive step, and are capable of industrial application. *Module Two: Biotechnology and Intellectual Property* provides more details about the legal requirements for patenting. Patents are granted through national patent offices, such as IP Australia. The process requires the filing of a patent application that discloses how to work the invention. This is published by the patent office and examined by a patent examiner to ensure that it meets the legal requirements for patenting. If the patent meets the legal requirements of novelty, inventive step and industrial application, and there is no opposition, a patent is granted. More detail on the application process for patents is in *Module Three Reading a Biotechnology Patent and the Patent Process*.

The Bt gene in seed distributed by Monsanto is protected by Australian Patent Number 638 438. The patent provides for:

a modified chimeric gene containing a promoter which functions in plant cells operably linked to a structural coding sequences and a 3’ end wherein structural coding sequences encodes an insecticidal protein of *Bacillus thuringiensis*, wherein the naturally occurring DNA sequence of said structural coding sequence has been modified without changing the protein coded for by the sequence in a method comprising removing the occurrence of more than 5 consecutive adenine and thymine residues.

The patent describes the process for modifying existing genes or for creating totally synthetic genes by removing or modifying ATITA sequences that have prevented expression of the bacterial genes in plants through providing misleading gene control signals when expressed in the plant genome. These A-T rich sequences are modified by use of synthetic oligonucleotides, which maintain the proper amino acid sequences while altering the underlying DNA, and while also bringing the A+T ratio towards 50% (typical of plants, but not Bt in its natural state.)

The 39 claims of the patent cover the inventive concept in different ways:

- claims 1-13 refer to modified chimera genes
- claims 14-26 refer to variation of claim 3 and related plant vectors
- claims 27-35 relate to methods for improving heterologous gene expression in plants through modification of the promoter sequence
- claim 36 extends the claims to plant cells
- claim 37 extends claims 36 to plant cells of soybean, cotton, alfalfa, oilseed, rape, flax, tomato, sugarbeet, sunflower, potato, tobacco, maize, rice and wheat
- claim 38 extends claims 36 and 37 to whole plants, and
- claim 39 extends claims 1-24 and 26 to seeds.

Despite the scope of this patent, several other firms have developed and patented their own Bt technology. These firms include Aventis CropScience, Marrison Merrel Dow and AgrEvo.

INGARD® Technology Users' Agreement

Monsanto's Bt-containing seed may only be used by growers who have a current Technology Users' Agreement with Monsanto Australia Ltd, which governs how the Bt technology has to be used, including such issues as resistance management. Any use of the ingard technology that contravenes the Agreement is subject to claims of patent infringement and/or breach of Agreement. A copy of the Technology Users' Agreement is at Attachment 3. Monsanto's development of such an agreement is a unique commercialisation strategy in the seed market to get a viable financial return on the R&D expenditure it spent developing the Bt gene.

The Technology Users' Agreement requires users to manage the technology, including applying a Resistance Management Plan, through::

- refuges: each grower is required to grow a refuge crop within the farm unit growing INGARD cotton
- planting window: all INGARD crops and cotton refuges must be planted and watered up within the period nominated in the Plan
- post harvest crop destruction: post-harvest crop destruction and removal of germinating volunteer cotton should be undertaken, as specified in the Plan
- pupae destruction: heliothis pupae must be destroyed by soil cultivation after harvest, as detailed in the Plan, and
- trap crops: each grower is required to plant a trap crop within the farm unit growing INGARD cotton.

The Technology Users' Agreement was developed in order to enable Monsanto to track how the crop is used and its impact on the environment. Monsanto must report on this to comply with the regulatory approvals it has. As such it must have a method of making sure that growers report the required data. Monsanto keeps this data confidential.

Trade mark protection for INGARD

A trade mark is a sign used to distinguish goods or services from the goods or services of another trader. A trade mark is infringed if a person uses, as a trade mark, a sign that is substantially identical to or deceptively similar to the registered trade mark. Trade marks do not need to be registered to get legal protection. However, registered trade marks are usually easier to enforce. Please see *Module One: Introduction to Intellectual Property* for more detail on trade marks.

The INGARD trade mark has been registered in Australia in two formats:

First, the trade mark is protected as the bare word 'INGARD.' This has been registered as trade mark number 658865, in respect of "genes for use in agriculture or horticulture, in particular, insect-tolerant genes for use in agricultural or horticultural seeds, and as trade mark number 658866 in respect of "genetically modified seeds, in particular, genetically modified agricultural or horticultural seeds which are insect-tolerant." This registration is subject to the endorsement that: It is a condition of registration that the word INGARD will not be used as the name, or part of the name, of a plant variety. These registrations are based on applications made in 1995.

Second, it is protected as a combination mark comprising the word INGARD and a stylized cotton logo together. This is registered under number 744265, based on an application made in 1997, in respect of:



- genes for use in agriculture or horticulture, including, insect-tolerant genes for use in agriculture or horticulture seeds being goods in this class
- cotton fabrics, piece goods of cotton and cotton blends; bed sheets; bed spreads; bed linen; table cloths; towels; blankets; handkerchiefs; all made wholly or in substantial part of cotton
- clothing, footwear and headgear
- agricultural products; cotton seed; unprocessed cotton seed oil; plant seeds; plants; seedlings; all the foregoing goods being goods included in this class

This registration is also subject to the endorsement that the word INGARD will not be used as the name, or part of the name, of a plant variety. This endorsement is aimed at ensuring that the trade mark owner cannot gain a continuing monopoly over the use of the common term used to designate a plant variety, given that the variety should be free for all to use once any plant breeder's rights have expired (see *Module Seven: Plant Breeder's Rights*).

This same product was commercialized in other countries using the trade mark BOLLGARD. It appears that it was originally not possible for Monsanto to use the BOLLGARD trade mark in Australia, because another company had already registered the trade mark BOLLGARD, under registration 608603 dating from 1993, in respect of pesticides, herbicides, fungicides and insecticides. In 1995, Monsanto applied for registration of the word trade mark BOLLGARD in respect of "genetic material for use in agriculture or horticulture, in particular, insect-tolerant genes or other such genetic material for use in agricultural or horticultural seeds; and all other goods in Class 1" (application 654595); and for "genetically modified seeds, in particular, genetically modified agricultural or horticultural seeds which are insect-tolerant; and all other goods in class 31" (application 654596). These applications were later withdrawn, possibly because of the conflict with the earlier registration 608603 of BOLLGARD in the name of the other company.

However, the other company's trade mark registration 608603 was cancelled in the year 2001 on the grounds that it had not been used. It is a general principle in trade mark law that a registration can be liable for removal or cancellation if the registered owner of the trade mark is not using it for the goods or services for which it has been registered. Once the registration has been cancelled, it opens up the possibility for others to use and register the trade mark. In fact, Monsanto has applied again for registration of BOLLGARD, and this application has very recently been approved for registration in Australia, presumably following the cancellation of the unused trade mark. This might clear the way for Monsanto to use the same trade mark in Australia as elsewhere.

To illustrate some of the issues associated with registering BOLLGARD as a trade mark, a decision of the European trade mark authority (OHIM) is provided at Attachment Four.

Plant breeders' rights protection for new varieties using the Bt gene

Plant breeders' rights are a separate type of intellectual property rights that give plant breeders the right to protect new varieties of plants. Under the Australian *Plant Breeder's Rights Act 1994*, a "plant" includes all fungi and algae but does not include bacteria, bacteroids, mycoplasmas, viruses, viroid and bacteriophages. The Act provides that a plant breeder's rights include the rights to:

- produce or reproduce the propagating material
- condition the propagating material for the purpose of propagation
- offer the propagating material for sale
- sell the propagating material

- import the propagating material
- export the propagating material, and
- stock the propagating material.

In order to get plant breeder’s rights, a new variety must be **distinct** from other known varieties, the characteristics of the variety must be **uniform** and they must be **stable** of different seasons of planting. These requirements are called the “DUS” requirements. New varieties are examined to check that they comply with the DUS requirements. Please see *Module Six: Plant Breeders’ Rights* for more information.

Plant breeders’ rights do not apply to genes. Therefore the actual Bt gene is not protected by plant breeders’ rights. Similarly, plant breeders’ rights do not apply to bacteria – so a new strain of the *Bacillus thuringiensis* bacterium could not be protected by plant breeders rights. However, new plant varieties that contain the Bt gene can be protected by plant breeders’ rights provided they meet the DUS criteria. As can be seen from the table below, out of 31 varieties of cotton (*Gossypium Hirsutum*) on the Plant Breeders’ Rights database only five of these seem to be directly Bt related. All of these were registered in 1996.

Name of applicant	Number of Bt cotton varieties	Total number of cotton varieties
CSIRO Plant Industry	5	22
Delta Pine Australia Pty Ltd	0	5
D&P Technology Holding Corporation	0	2
Delta and Pine Land Company	0	1
Mrs Kamila Ullman and Professor VN Fursov	0	2

What Health and Safety Regulatory Frameworks Affect INGARD Cotton?

An important point to remember is that the grant of a patent or plant variety right does not give you a right to market your invention. Technology that is protected by IP rights is still subject to Government regulations, such as regulations on environmental protection, health and safety. Accordingly, even though Monsanto got patent protection for the Bt gene and trade mark protection for “INGARD®” it was unable to market INGARD® cotton until it had also got all the necessary Government regulatory approvals. Before Monsanto commercialised Bt cotton it needed to get regulatory approval from:

- the National Registration Authority
- the Genetic Manipulation Advisory Committee (GMAC), and
- the Australian and New Zealand Food Authority (ANZFA).

Each of these regulatory frameworks is discussed below. If any of these regulatory bodies had not approved the marketing of Bt cotton, Monsanto’s patented invention, INGARD® cotton, would not have been able to be sold. For this reason it is very important to consider which regulatory frameworks are relevant to your invention during your research to make sure that you will comply with their requirements.

Registration of the Bt gene with the National Registration Authority

The INGARD gene is registered with the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), under the Agricultural and Veterinary Chemicals Code. The NRA Approval No for INGARD is 48296/0997.

The NRA assesses all agricultural and veterinary chemicals before they can be marketed in Australia. The NRA requires full data packages on chemistry/stability, toxicology, residues, trade, metabolism, occupational health and safety, efficacy, crop safety, environmental fate and ecotoxicology before granting approval. New plant varieties are not normally required to be approved by the NRA, but INGARD cotton required registration because its leaves are a pesticide/insecticide.

In addition, the NRA requires ongoing reporting as a condition of registration. For example, Monsanto must detail product performance and grower compliance determined from industry audits, research and surveillance to ensure the continuing registration of INGARD with the NRA.

Fees are imposed by the NRA under the Agricultural and Veterinary Chemicals Act 1994, and vary depending on the complexity of an application. For example, a primary application taking 15 months to assess is charged at \$20,620 whilst a new product similar to one already registered may take only 3 months to assess and is levied at \$620. To continue registration, payment of registration renewal fees is required.

Genetic Manipulation Advisory Committee

The Genetic Manipulation Advisory Committee (GMAC), was a statutory body established by the Australian Government to:

- oversee the development and use of innovative genetic manipulation techniques in Australia so that any biosafety risk factors associated with the novel genetics of manipulated organisms are identified and can be managed; and
- to advise the Minister about matters affecting the regulation of innovative genetic manipulation technology.

The responsibilities of GMAC extended to all techniques that can transfer genetic material between species that may not normally exchange genetic material in natural circumstances, and to non-traditional techniques capable of modifying the genetic material of organisms. GMAC was concerned with risk factors associated with the altered genetic capabilities of a genetically modified organism (GMO), which may give rise to safety concerns in public health and safety, agricultural production, and the quality of the environment.

INGARD® cotton was approved by GMAC for use in limited areas in 1996. It needed to be approved by GMAC because of the transgenic nature of the modified cotton and the potential for environmental impact. As you can see from the table below, almost 90 cotton trials have been approved by GMAC since 1995.

Trial applicant	Number of trials	Years trials conducted
CSIRO Division of Plant Industry	45	1993-2001
Deltapine Australia	31	1993-2000
Cotton Seed Distributors	6	1998-2000

Agriculture Western Australia	2	1998-1999
CSIRO Division of Entomology	2	1998, 1999
Applied Horticultural Research	1	1997
Monsanto	1	1999-2000

Following the passage of a revised legislative framework for regulation of gene technology, the *Gene Technology Act 2000*, GMAC has been replaced by the office of the Gene Technology Regulator (OGTR), with responsibilities including approval of genetically modified organisms. The OGTR therefore has continuing responsibility for regulation of the use of the INGARD gene technology.

Australia and New Zealand Food Authority

The Australia and New Zealand Food Authority (ANZFA) is responsible for approval of genetically modified food in Australia and New Zealand. Bt cotton has been registered with ANZFA and approved for sale. This was necessary because one of its processed products, cotton seed oil, is used for human consumption.

ANZFA had issued guidelines for the safety assessment of foods to be produced using gene technology. ANZFA assessed the following safety issues:

- the direct consequences of new gene products in food encoded by genes introduced during genetic modification including physiochemical characteristics, allergenicity, impact on nutritional status,
- the direct consequences of altered levels of existing gene products encoded by genes introduced or modified during genetic modification
- the indirect consequences of the affect of any new gene or gene products including modification of the expression of another gene or modification of the metabolic pathways of other genes or their products
- the possibility of gene transfer from ingested genetically modified organisms and/or food or food components derived from them, including the potential consequences of transfer of an introduced gene into the micro-organisms into the human get, and
- the potential for adverse health effects associated with genetically modified micro-organisms including their ability to compete for nutrients and to alter intestinal flora in humans.

Who are the Key Players in INGARD Cotton?

Apart from gaining the necessary regulatory approval, it was also necessary to find appropriate technical, commercial and legal pathways to the commercialisation of the Bt gene technology in cotton. This meant that a complex relationship between various partners was necessary. The key players involved in the commercial development of INGARD cotton in Australia are.

- Monsanto: the owners of the Bt patent and the INGARD® trade mark
- CSIRO: the public sector research institution which owns variety rights on cotton germplasm
- Cotton R&D Corporation: the research funders, and
- Cotton Seed Distributors and Delta Pine: two commercial seed firms.

The role of each of these bodies is set out below.

Monsanto

Monsanto is a global life sciences company that makes and markets high-value agricultural products, pharmaceuticals and food ingredients. It has included insect resistance management as an integral part of its development of crops protected against insect pests. Monsanto believes that “resistance management is more than ‘good citizenship’; it also preserves the value of products that have taken years to develop”.

Monsanto researchers commenced work with *Bacillus thuringiensis* (Bt) in 1985. In 1989, scientists at Monsanto spliced the gene from Bt into cotton plants. Their research also enabled them to increase the expression of the gene one thousandfold. It was clear that the process had commercial potential as the greatly increased levels of the Bt toxin expressed in cotton plants with INGARD® killed caterpillars in greenhouse tests at levels equal to or better than leading insecticides.

Field tests began in the US in 1990. Australian varieties of INGARD were developed by importing a ‘parental’ line containing the gene from Monsanto USA into Australia in 1992. The gene was then crossed and backcrossed with the best Australian varieties, thus transferring the INGARD gene into CSIRO and Deltapine (DP) varieties.

In addition to INGARD cotton, Monsanto Australia Ltd is currently developing Roundup Ready® Cotton, INGARD cotton containing two Bt genes, and Roundup Ready® Canola for use by Australian farmers. Monsanto has applied to the Australian Government for permission to import products derived from genetically modified crops grown overseas. These include Roundup Ready soybean, Roundup Ready canola, Bt corn, Roundup Ready corn, Bt potato, and Bt potato with leaf roll virus.

Cotton Research and Development Corporation

The Australian Cotton Research and Development Corporation (CRDC) was established in 1990 under the *Primary Industries and Energy Research and Development Act 1989*. The role of the CRDC is to increase the contribution that R&D makes to the cotton industry and the community in general. The Corporation aims to achieve this goal by developing efficient, sustainable production systems, improving fibre quality to better meet market needs, and developing efficient handling, transport and marketing systems and infrastructure.

The primary functions of the CRDC include:

- investigating and evaluating the research and development requirements of the cotton industry
- preparing, reviewing and revising a research and development plan for the cotton industry
- monitoring, evaluating and reporting to Federal Parliament, the Minister for Primary Industries and Energy and ACGRA on research and development activities with which the CRDC is involved, and
- facilitating the dissemination, adoption and commercialisation of the results of cotton research and development (section 11 of the *Primary Industries and Energy Research and Development Act*).

The CRDC administers about 40% of all cotton R&D funding in Australia. Each year about \$6m is allocated to over 100 projects addressing a wide range of issues associated with cotton production. Funds for projects administered by CRDC are from industry and the Australian Government. Growers contribute a levy of \$1.75 per 227 bale which is matched by the government on a dollar for dollar basis up to 0.5% of the value of the industry’s gross production of cotton lint. Income is also generated from a share of royalties on the seed sales of CSIRO-bred cotton varieties.

INGARD cotton is an important part of the CRDC’s Integrated Pest Management plan. CRDC funded CSIRO for some of its research into the development of varieties using the INGARD technology. During the commercial and experimental trial stages for INGARD in Australia, the CRDC represented the views of local growers concerning licence fees for use of INGARD cotton in Australia.

CSIRO Division of Plant Industry

The Commonwealth Scientific and Industrial Research Organization (CSIRO) is the principal public sector research institution in Australia, with a wide range of activities and specific expertise in agronomy and plant biotechnology. Today, more than 90% of Australia's cotton is grown from seed developed by CSIRO. The Cotton Research Unit (CRU) at CSIRO has imported many hundreds of varieties from around the world and evaluated them in Australia for useful characteristics. These are incorporated into the cotton breeding programs at CSIRO to produce new plant varieties.

Varieties of cotton containing the Bt gene were developed by CSIRO and its commercial partners including Monsanto and Cotton Seed Distributors (CSD). The aim of the research was to develop cotton varieties with built in pest resistance to suit Australian conditions. Annual field trials of six transgenic varieties expressing the toxin gene began in the 1992/93 cotton season. The aims were to evaluate the effectiveness of the plants in killing larvae when grown under field conditions, and to commence studies of the impact of this cotton on other insects and the environment.

CSIRO has also collaborated with Cotton Seed Distributors (CSD), Monsanto and Rhone Poulenc, who are at the forefront of development technologies for new varieties.

Australian Cotton Cooperative Research Centre (CRC)

The Australian Cotton Cooperative Research Centre (CRC) commenced operations in 1997. The Cotton CRC is funded by the Australian Government. The organisation is located within the CSIRO's Cotton Research Institute at Narrabri in NSW. The purpose of the Cotton CRC is to enhance the development and growth of the Australian cotton industry through collaborative research, education and the adoption of sustainable farming systems which are environmentally responsible, increase the reliability of production and increase market competitiveness.

The Cotton CRC is a collaborative structure involving:

- CSIRO Division of Plant Industry, Division of Entomology, Division of Tropical Agriculture and Division of Textiles and Fibres
- NSW Department of Agriculture
- Queensland Department of Primary Industry
- Agriculture Western Australia
- Northern Territory Department of Primary Industry and Fisheries
- Cotton Research and Development Corporation
- Cotton Seed Distributors
- Queensland Cotton
- Western Agricultural Industries
- Twynam Cotton
- the University of New England, and
- the University of Sydney.

The CRC is an unincorporated joint venture hence agreements for R&D program are negotiated by the participants under the CRC umbrella, rather than by the CRC. There will be no legal agreements between companies such as Monsanto and the CRC itself.

Cotton Seed Distributors

Cotton Seed Distributors (CSD), is a grower-controlled organisation based in Wee Waa, New South Wales. It is Australia's largest supplier of commercial cotton seed. It has been developing new varieties of cotton since it was established in 1967.

During the 1998/99 season, Cotton Seed Distributors established a total of 52 variety trials, consisting of 32 conventional and 13 INGARD® trials, spread across all the cotton growing regions in Australia. These trials are undertaken by CSD agronomists, to ensure that the trials are

conducted in accordance with the Cotton Research and Development Corporation (CRDC) protocols. Members of the CSIRO cotton plant breeding team and CSIRO extension team also regularly monitor varietal performance in the trial during the season.

CSD and CSIRO have collaborated to provide cotton varieties with improved performance. Innovation has been a consuming focus of the collaboration, which has seen the development of many cotton varieties of value to both the grower and value-added industries of spinning and yarn manufacture, aiming at making a substantial contribution to the cotton industry.

Deltapine Pty Ltd

The Delta & Pine Land Company (Deltapine), operates the oldest, continuous private cotton breeding program in the US. The company became US owned in 1978 after a British conglomerate sold its interests to US investors. Deltapine became a publicly listed company on the NASDAQ Exchange in 1993. In 1995 it moved its listing onto the New York Stock Exchange [DPL].

The company is involved in the breeding of conventional and new transgenic cotton and soybean varieties. It controls 56 test locations across America. The company also controls 4000 conventional varieties in yield tests and 1,400 transgenic lines in yield trials. Deltapine's product list includes conventional varieties of cotton planting seed as well as transgenic varieties.

Deltapine was the first company to introduce transgenic cotton seed featuring the Bollgard or Bt gene technology under licence from Monsanto.

What was the process of commercialising INGARD cotton?

Monsanto developed commercial relationships with a range of different parties in the process of commercialising INGARD cotton. This is an important practical point. The commercialisation process often requires you to build relationships with other people. This is the case whether you are a backyard inventor or part of a multinational corporation. You need assistance from other people because you might not have all the technology, skills, time or financial resources to commercialise your invention alone.

Despite spending many years researching and developing the Bt gene and its expression in plant systems, and gaining patents on its research outcomes, Monsanto did not have access to suitable germplasm necessary to develop new varieties of cotton bearing the gene for production in Australia. It therefore needed to find partners with whom it could develop new varieties for sale to commercial growers. Figure 1 sets out the relationships that enabled commercialisation of cotton in Australia with the INGARD gene technology.

Monsanto's relationship with CSIRO

As noted above, Monsanto developed the Bt technology. However, it did not have the germ plasm required to develop new varieties of plant and therefore seed.

The Australian CSIRO was aware of Monsanto's work in the US developing new cotton varieties and approached Monsanto about collaboration. CSIRO held the germ plasm which could then be combined with the Bt gene to develop varieties suited to Australian conditions. In Australia, CSIRO is Monsanto's main research partner. It has R&D contracts with Monsanto to undertake research using the BT gene and promoter sequences.

CSIRO needed to negotiate a separate arrangement with Monsanto to be in a position to commercialise the R&D through its business partner, Cotton Seed Distributors. In theory, the technology holder could refuse to extend the license for commercial purposes – there may be concerns about product liability or such issues as resistance management. In other cases in Australia, research institutes have secured a license to use technology for research, but have been refused extensions of the license for commercial use. CSIRO now includes in its research planning consideration of the route to market for proposed research outcomes, including protection of the IP it generates and strategies for negotiating

CSIRO's relationship with its funding body

CSD pays a royalty to CSIRO for developing the varieties for commercial release. As the Cotton R&D Corporation has funded some of the CSIRO's research into using Bt in Australian cotton varieties, CSIRO also pays a royalty back to CRDC for this support.

Monsanto's relationships with commercial seed distributors

Usually, the seed market is high volume and low profit – similar to most commodity markets. Thus despite spending many years researching and developing the Bt gene and its expression in plant systems, it would have been difficult for Monsanto to have launched its own seed variety to sell into a market which was used to paying low prices for seed. This is why Monsanto developed the concept of combining payment for the seed with licences for the technology itself.

Cotton Seed Distributors and Deltapine are major commercial seed distributors and as shown in the diagram above they both have a licence from Monsanto to use the Bt gene promoter in cotton varieties.

Cotton Seed Distributors has two licences. It has an exclusive licence from CSIRO for its cotton varieties and a separate licence from Monsanto to use the Bt gene promoter contained in these varieties. Deltapine imports cotton varieties from overseas and has a local breeding program to develop varieties suitable for the Australian market so it does not need a licence from CSIRO for cotton varieties. However, Deltapine does have a licence from Monsanto to use the Bt gene promoter contained in the Bt cotton varieties that it breeds.

Monsanto's relationship with growers

The growers purchase the cotton seed direct from either Deltapine or Cotton Seed Distributors. However, they also must sign a Technology User Agreement and provide a payment direct to Monsanto that is designed to reimburse Monsanto for its R&D in developing gene technology. The Technology User Agreement also binds the growers to collect data for Monsanto's use in its reports to the regulatory agencies that control commercialisation of genetically modified plants.

Costs of research, breeding and regulatory approvals

In any commercial decisions by companies like Monsanto, the cost of breeding programs and the regulatory process needs to be taken into account in addition to the cost of the research. In addition to the approximately \$100 million that Monsanto has spent on its R&D, it costs a further \$5 million to develop breeding programs for any new varieties and an equivalent amount of the product development pathway and regulatory requirements. Thus the size of the crop grown in Australia, or any other country is likely to affect a business decision by a large corporation regarding release this or similar gene technology. Regulatory fees are the same for every release of a new plant variety, whether or not a similar technology has been released before. Thus even though Bt cotton is approved for release in Australia, developers of any other variety would have to go through the same processes with the Office of the Gene Technology Regulator to have another crop with Bt genes approved for commercial use.

Field performance of INGARD cotton

Since the commercial release of INGARD® was approved in 1996 the field performance of INGARD cotton has been extensively reviewed. The performance of INGARD has not been as expected by CSIRO, Monsanto and the cotton industry, although it has provided benefits to the cotton grower and the community through the use of reduced insecticides. According to one official report:

GM crops have the potential to reduce the need for toxic chemical sprays. In Australia in the 1998/1999 season, INGARD® (insect-resistant) cotton (the only GM crop currently released commercially in Australia) required 44% fewer pesticide sprays than conventional cotton.

Some aspects of this case study

This section provides a brief overview of a very complex process and set of relationships. Some distinctive features of this case study are:

- Licensing of the INGARD gene technology to cotton growers through the Technology User Agreement, separately from the sale of seed, and the creation of a distinct royalty stream reflecting the value of the technology as such apart from the underlying cotton seed;
- The overlap between public and private sector activities, and the need for commercial relationships to provide support both for the cost of research and development and for the regulatory approval processes such as field tests and toxicity tests required before release to growers;
- The need for research organizations to consider the longer-term needs of commercialisation, and freedom to operate in making their new technologies available for general use, apart from negotiation of agreements for use of technology in research and development;
- The relationship between licensing of IP rights and the legal mechanism of a contract between technology provider and technology user, on the one hand, and a program of technology management including monitoring use to check compliance with environmental regulations and managing resistance, on the other hand;
- The need for the technology developer (the Bt gene and promoter) to cross-license or otherwise get access to platform technologies which are necessary for the successful application of the new technology;
- The practical implications of freedom to operate considerations and IP management for those funding and undertaking research, including public sector institutions, and
- The need for public sector researchers and funding agencies to manage the costs of regulatory approval, particularly for products which are for smaller or more specialised applications where private sector players are unlikely, for commercial reasons, to cover compliance costs and bear other risks.

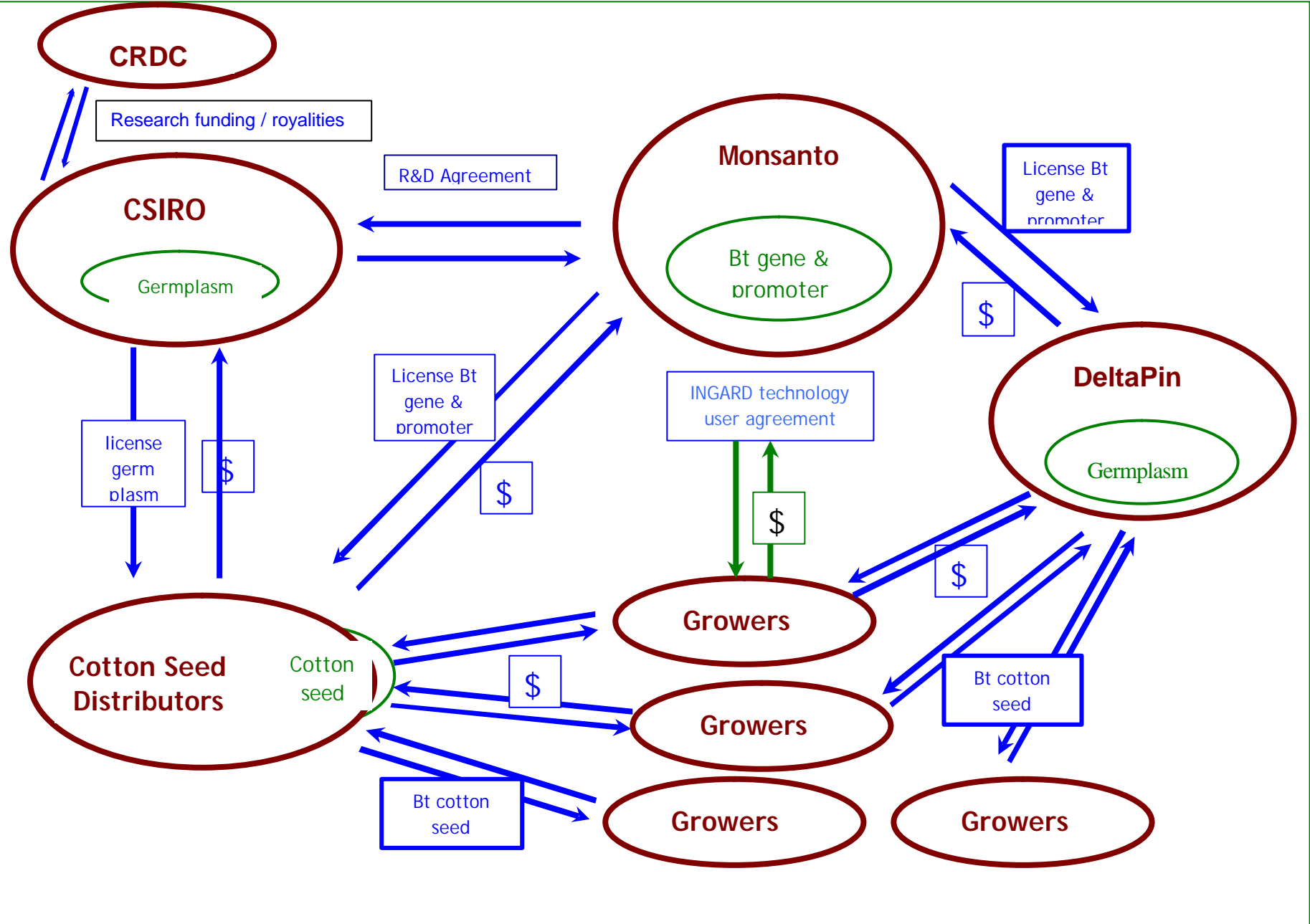


Figure 1: Relationships in Bt

10.5 Group Exercises on “Bt Cotton” Case Study

Please discuss the Bt Cotton case study with your fellow participants and prepare answers to the following questions.

Exercise 10.5.1 - patents compared with plant breeders’ rights

Monsanto got patent protection for the Bt gene. Why couldn’t Monsanto get plant breeders’ rights protection for the Bt gene or for plant varieties including Bt cotton?

Exercise 10.5.2 - Monsanto’s licence arrangements for use of the Bt gene

Why do you think that Monsanto licenses use of the Bt gene, rather than commercialising the invention on its own?

Exercise 10.5.3 - building relationships in commercialising an invention

Why did Monsanto and CSIRO develop a commercial relationship in the development of Bt cotton? What did Monsanto need from CSIRO?

Exercise 10.5.4 - regulatory approvals for Bt cotton

- (i) What regulatory approvals did Monsanto need to commercialise Bt cotton?
- (ii) Imagine that Monsanto had failed to get regulatory approval to market Bt cotton. If this had happened, do you think that Monsanto could have marketed Bt cotton anyway because it had a patent? Why?

Exercise 10.5.5 - Monsanto’s Technology Users’ Agreement

Why did Monsanto develop the Technology Users’ Agreement? What are its purposes?

Exercise 10.5.6 - Bt cotton and CSIRO

What do you think are some advantages and disadvantages for CSIRO from the way in which Monsanto has commercialised the Bt gene?

Exercise 10.5.7 - Bt cotton and Cotton Seed Distributors

What do you think are some advantages and disadvantages for Cotton Seed Distributors from the way in which Monsanto has commercialised the Bt gene?

Exercise 10.5.8 - Bt cotton trade marks

- (i) What trade marks have been used in relation to Bt cotton? Why did Monsanto use a different trade mark in Australia and in other countries? What legal options were open to it to bring its Australian mark into line with the other countries?
- (ii) What goods were covered in the registration of the INGARD logo? What does this suggest about the possible commercialisation of this invention?

10.6 Summary of Module Ten

Commercialising your invention is a way to get possible financial benefits from your work. The Eternal® Papayas and Bt Cotton Case Studies show you how it can be done. The checklist below sets out key steps for commercialising an invention. Other Modules give details about these steps:

Module One: Introduction to Intellectual Property Law gives an overview of the types of intellectual property.

Module Two: Biotechnology and Intellectual Property sets out the legal requirements for getting a patent.

Module Three: Reading a Biotechnology Patent and the Patent Process sets out the administrative steps to get a patent.

Module Four: Searching Patent Databases sets out how to track down technical information to help your research.

Module Five: Group Exercise on Patent Validity: Neem gives you practical experience in reading and analysing a patent.

Module Six: Group Exercise on Patent Validity: Relaxin provides similar experience in relation to a more complex pharmaceutical patent involving DNA-related claims and ethical issues.

Module Seven: Plant Breeders' Rights sets out details about plant breeders' rights.

Module Eight: Researching and Intellectual Property Rights sets out how to develop a R&D and IP strategy, get freedom to operate, and negotiate contracts with commercial partners.

Module Nine: Licensing and Enforcing Intellectual Property Rights tells you how to make the most of your intellectual property by exploiting and protecting it.

This Module brings it all together.

Commercialisation Checklist

How to Take Your Invention from the Laboratory to the Marketplace

- ✓ **Develop a combined R&D and IP strategy** at the start of your research to make sure that you will be able to get IP rights and benefit from commercialising your invention if your research is successful, e.g. keep your invention secret until you apply for a patent!
- ✓ **Do a patent survey** to see what research has already been done and what existing IP rights might affect the use of your research outcome.
- ✓ **Create a new invention!**
- ✓ **Get intellectual property protection** for your invention, such as a patent or plant breeders' rights
- ✓ **Keep a track of the costs of your invention** to help you decide whether or not to commercialise it and help you to work out a price for it if you do
- ✓ **Do business research before commercialisation** to check demand for your invention, to find out health and safety regulatory requirements in the countries you want to market your invention, and to check out commercial partners who might want to licence or buy your invention
- ✓ **Decide which model of commercialisation is best for you** such as licensing, assignment or joint venture
- ✓ **Establish "freedom to operate"** to make sure that commercialising your invention will not infringe someone else's patent rights
- ✓ **Enforce your valuable intellectual property rights**
- ✓ **Get expert advice** when you need it.

10.7 Attachments

Attachment 1: Patent Rights Potentially Relevant to 'Papaya' Technology

Attachment 2: Relevant Patent Claims for Eternalâ Papayas

Attachment 3: INGARDâ Technology User Agreement 1999/2000

Attachment 4: OHIM decision on the BOLLGARD trade mark

Attachment 1: Patent Rights Potentially Relevant to “Papaya” Technology*

Technology	Assignee	PCT	Australia	Malaysia	USA	Europe	Others ¹	~ Expiry
Ripening-related ACS gene								
ACC Synthase genes	US Dept of Ag	WO92/044 56	AU-B-85994/91	no filing	5,723,766 5,923,766	0 548 164 A4	MX; CA; JP	2012 Mar 2105 (USA)
ACS from papaya	University of Qld	WO97/111 66	AU-A- 69200/96	PI 9603895	Allowed	pending	TA: 033348	Sept 2016
<u>ACS from papaya</u>	University of Hawaii				5,767,376			
Selectable marker gene								
<i>nptII</i> gene	Monsanto	WO84/029 13	no separate filing; included in AU-B-24363/84	no filing	5,034,322	0 131 623 B2 (same as for 35S) Opposition Decision appears to be in appeal	JP	Jan. 2004 July 2008 (USA)
Promoters								
maize ubiquitin I promoter	Mycogen (Dow AgroSciences)		no filing	?? check	5,510,474 5,614,399	0 342 926 B1 appears to have lapsed in AT; SE; C	CA; JP	May 2009 Aug. 2014 (US) June 2015 (USA)
nopaline synthase promoter	Monsanto		no filing	no filing	5,034,322	0 131 623 B2 Opposition Decision appears to be in appeal	JP	Jan. 2004 July 2008 (USA)
CaMV35S promoter	Monsanto		no filing	no filing	5,352,605 5,530,196 5,858,742	0 131 623 B2 (same as for nptII) Opposition Decision appears to be in appeal	JP	Jan. 2004 Oct. 2011 (USA)

Technology	Assignee	PCT	Australia	Malaysia	USA	Europe	Others ¹	~ Expiry
Transformation								
Biolistics	DuPont de Nemours BioRad (for the apparatus, <i>per se</i>)		no filing	no filing	4,945,050 5,036,006 5,100,792 5,371,015	no filing	CA	Nov. 2005 (CA) July 2007 (USA) July 2008 (USA) Dec. 2011 (USA)
Binary Vector System	MOGEN		no filing	no filing	4,940,838 5,464,763	0 120 516 B1 0 159 418 B1	JP	Feb. 2004 July 2007 (USA)
<i>Agrobacterium</i> -mediated	Max-Planck-Institute		AU-B-23274/84 (546542)	no filing	in interference proceedings before the US PTO	0 116 718 B2 0 290 799 A3 0 320 500 A3 status unclear; both seem to be pending	JP; IL JP JP	Jan. 2004 unknown (USA)
<i>Agrobacterium</i> -mediated	Monsanto		AU-B-24363/84 (559562)	no filing	in interference	0 131 620 B1 (method/seed) 0 131 624 B1 (plasmids)	JP	Jan. 2004 unknown (USA)
Down-regulation								
antisense	Calgene (Monsanto)		AU-B-70597/87 AU-A-13017/92 AU-A-44470/93 both lapsed	no filing	5,107,065 5,453,566 5,759,829	0 240 208 B1 seems to be in opposition 0 485 367 A1	CN; IL; JP; NZ	Mar. 2007 Apr. 2009 (USA) Jan. 2006 (USA) Apr. 2009 (USA)
co-suppression (Transwitch)	DNA Plant Technology Corp.		AU-B-54123/90	no filing	5,034,323 5,231,020 5,283,184	0 465 572 B1 0 647 715 A1 (status not checked)	JP	Mar. 2010 July 2008 (USA) July 2010 (USA) July 2010 (USA)
double hybrid	CSIRO	WO99/53050						

¹ CA = Canada; JP = Japan; MX = Mexico; TA = Thailand; CN = China; IL = Israel; NZ = New Zealand

Attachment 2: Relevant Patent Claims for Eternalâ Papayas

BVS patent claims: US 4,940,838

1. A process for the incorporation of foreign DNA into chromosomes of dicotyledonous plants, comprising infecting the plants or incubating plant protoplasts with Agrobacterium bacteria, which contain plasmids, said Agrobacterium bacteria containing at least one plasmid having the vir-region of a Ti plasmid but no T-region, and at least one other plasmid having a T-region with incorporated therein foreign DNA, but no vir region.

BVS patent claims: EP 0 120 516

1. A process for the incorporation of foreign DNA into chromosomes of dicotyledonous plants, comprising infecting the plants or incubating plant protoplasts with Agrobacterium bacteria, which contain plasmids, said Agrobacterium bacteria containing at least one plasmid having the vir-region of a Ti plasmid but no T-region, and at least one other plasmid having an artificial T-region with only foreign DNA between the 23 base pairs at the extremities of the wild type T-region, but no vir-region, the vir-region plasmid and the T-region plasmid containing no homology which could lead to co-integrate formation.

BVS patent claims: EP 0 159 418

1. A process for the incorporation of foreign DNA into the genome of monocotyledonous plants, by infecting the monocotyledonous plants or incubating the protoplasts thereof with Agrobacterium or Rhizobium bacteria containing a virulence region and at least one T-region originating from a Ti plasmid or a Ri plasmid or both, which T-region is provided with said foreign DNA.

nos-nptII patent claims: US 5,034,322

1. A chimaeric gene capable of expressing a polypeptide in a plant comprising in sequence:
 - (a) a promoter region from a gene selected from the group consisting of an Agrobacterium tumefaciens opine synthase gene and a ribulose-1,5-bis-phosphate carboxylase small sub-unit gene;
 - (b) a structural DNA sequence encoding a polypeptide that permits the selection of transformed plant cells containing said chimaeric gene by rendering said plant cells resistant to an amount of an antibiotic that would be toxic to non-transformed plant cells, said structural gene sequence being heterologous with respect to the promoter region; and
 - (c) a 3' non-translated region of a gene naturally expressed in plants, said region encoding a signal sequence for polyadenylation of mRNA.

nos-nptII patent claims: US 5,034,322

2. A gene of claim 1 in which the polypeptide renders transformed plant cells resistant to an amount of an aminoglycoside antibiotic that would be toxic to non-transformed plant cells.
3. A gene of claim 2 in which the polypeptide is a neomycin phospho-transferase.
4. A gene of claim 1 in which the 3' non-translated region is selected from a gene from the group consisting of the genes from the T-DNA region of Agrobacterium tumefaciens.
5. A gene of claim 1 in which the 3' non-translated region is from the nopaline synthase gene of Agrobacterium tumefaciens.

CaMV35S patent claims: US 5,352,605

1. A chimaeric gene which is expressed in plant cells comprising a promoter from a cauliflower mosaic virus, said promoter selected from the group consisting of a CaMV (35S) promoter isolated from CaMV protein-encoding DNA sequences, and a structural sequence which is heterologous with respect to the promoter.
2. A chimaeric gene of claim 1 in which the promoter is the CaMV (35S) promoter.
3. A chimaeric gene of claim 1 in which the promoter is the CaMV (19S) promoter.

nos-nptII patent claims: EP 0 131 623

1. A chimaeric gene capable of expressing a polypeptide in plant cells comprising in sequence:
 - (a) a promoter region from a gene which is naturally expressed in plant cells
 - (b) a 5' non-translated region
 - (c) a structural coding sequence encoding a neomycin phosphotransferase polypeptide; and
 - (d) a 3' non-translated region of a gene naturally expressed in plant cells, said region encoding a signal sequence for polyadenylation of mRNA; said promoter being heterologous with respect to the structural coding sequence.
2. A gene of claim 1 in which the promoter is selected from a gene of the group consisting of a nopaline synthase gene and a ribulose-1,5-bis-phosphate carboxylase small sub-unit gene.
3. A gene of claim 1 in which the 3' non-translated region is selected from a gene from the group consisting of the genes from the T-DNA region of *Agrobacterium tumefaciens*.
4. A gene of claim 1 or 2 in which the 3' non-translated region is from the nopaline synthase gene of *Agrobacterium tumefaciens*.

During the Opposition Proceedings on EP 0 131 623, Claims 5-9 were deleted from the patent. Claims 5-9 were:

5. A chimaeric gene capable of expressing a polypeptide in plant cells comprising in sequence:
 - (a) a promoter region from a plant virus;
 - (b) a 5' non-translated region;
 - (c) a structural coding sequence;
 - (d) a 3' non-translated region of a gene naturally expressed in plants, said region encoding a signal sequence for polyadenylation of mRNA, said structural coding sequence being heterologous with respect to said promoter region.
6. A gene of claim 5 in which the promoter is from cauliflower mosaic virus.
7. A gene of claim 6 in which the 3' non-translated region is from a nopaline synthase gene.
8. A gene of claim 5 in which the promoter is the full-length transcript promoter of cauliflower mosaic virus.
9. A culture of micro-organisms identified by the ATCC accession number 39265.

Attachment 3: *INGARD* Technology User Agreement 1999/2000

THE PARTIES AGREE:

1 APPOINTMENT AS AN INGARD TECHNOLOGY USER

- 1.1 Subject to the terms and conditions of this Agreement, Monsanto hereby grants to the INGARD Technology User, and the INGARD Technology User accepts, a non-exclusive license (the "License") to exploit patent no. 638 438 and to purchase and use the INGARD Gene Technology (the "Gene Technology") on the farm unit nominated on the Grower Information Details sheet on Schedule 1 of this Agreement (the "Farm Unit" and "Grower Information Details Sheet" respectively) to grow one single cotton crop during the 1999/2000 growing season
- 1.2 The Licence is restricted to use by the INGARD Technology User and may not be assigned to or exercised by any other person, firm or corporation other than the INGARD Technology User.
- 1.3 The INGARD Technology User is not licensed to use cotton seed varieties containing the INGARD gene (the "INGARD Cotton Seed") other than on the conditions set out in this Agreement

2 OBLIGATIONS OF INGARD TECHNOLOGY USER

2.1 During the term of this Agreement, the INGARD Technology User agrees that in consideration of the license it must:

- (a) upon execution of this Agreement:
 - (i) complete the Grower Information details Sheet; and
 - (ii) provide a scaled map of the Farm Unit (showing surveyed fields) to the Technology service Provider nominated on the Grower Information details Sheet (the "Nominated TSP");
- (b) before ordering INGARD Cotton Seed from a cotton seed supplier, obtain a Purchase Authority from the Nominated TSP. The Nominated TSP may be unable to issue a Purchase Authority in respect of the entire required amount of INGARD Cotton Seed due to limitations on the total hectares available for the 1999/2000 season imposed by the regulatory authorities;
- (c) when applying for a Purchase Authority from the Nominated TSP, clearly indicate on the map referred to in clause 2.1(a)(11):
 - (i) the field intended to be planted with INGARD Cotton seed (together with the intended seeding rate and variety or varieties to be used); and
 - (ii) the type, size and location of the insect refuge required pursuant to the Resistance Management Plan for INGARD Cotton;
- (d) not resell or supply any INGARD Cotton Seed to any other party;
- (e) use INGARD Cotton Seed to plant only one crop for one growing season on the Farm Unit on an area which shall be greater than (or equal to) 20 hectares but less than (or equal to) 500 hectares or 25% of the Farm Unit (whichever is greater);
- (f) strictly comply with the label directions and ensure that the INGARD Technology User's consultants and contractors do likewise;
- (g) not save the seed produced from INGARD Cotton Seed for the purpose of use in cotton production nor sell any INGARD Cotton Seed (including the seed produced from INGARD Cotton) to anyone whom the INGARD Technology User knows or ought reasonably know intends or is likely to use or on-sell the INGARD Cotton Seed for the purpose of cotton production (the INGARD Technology User may, however, use or sell the seed produced from INGARD Cotton Seed where the INGARD Technology User bona fide believes the purchaser intends to use it as stock feed or for cotton seed oil production);
- (h) strictly follow the Resistance Management Plan for INGARD cotton;
- (i) allow Monsanto or the Nominated TSP reasonable access to review crop management records and to inspect and test any INGARD Cotton Seed located on the Farm Unit for the purposes of:
 - (i) assisting the INGARD Technology User to implement the Resistance Management plan for INGARD Cotton;
 - (ii) and ensuring compliance with this Agreement;
- (j) perform audits of the Farm Unit in the manner and at the times specified by Monsanto from time to time;
- (k) notify Monsanto of any change in the size of the Farm Unit or any other details
- (l) comply with all Federal, state and local laws, ordinances, rules, regulations, by-laws and policies applicable to the INGARD Technology User's performance of its obligations under this Agreement and all reasonable directions and instructions given by Monsanto.

If the INGARD Technology User ceases to purchase INGARD protection, the rights to inspect and test any INGARD Cotton or INGARD Cotton Seeds will continue for a period of three years after the last year in which the INGARD Technology User planted INGARD Cotton Seed.

3 ADDITIONAL INFORMATION

3.1 The INGARD Technology User acknowledges that when growing INGARD Cotton:

- (a) the control of *Helicoverpa armigera* and *H. punctigera* provided by INGARD Cotton may vary and require supplemental treatment by the INGARD Technology User in order to avoid economic damage;
- (b) such variation can occur even in circumstances where the INGARD Technology User has complied with Clause 2(f).

4. INTELLECTUAL PROPERTY RIGHTS

- 4.1 The INGARD Technology User acknowledges that any and all trade marks, copyrights, patents and any other industrial or intellectual property rights whether arising by reason of statute or at common law or in equity ("Monsanto Rights") (including without limitation unpatented production methods and technical and confidential information so long as they are not public knowledge) embodied in or used in connection with the INGARD Gene Technology or communicated pursuant to this Agreement, are and remain the sole property of Monsanto.
- 4.2 The INGARD Technology User must report immediately to Monsanto any apparent infringements of Monsanto's Rights by third parties which come to the notice of the INGARD Technology User. The INGARD Technology User agrees that it will cooperate in the conduct of any action brought by Monsanto.
- 4.3 The INGARD Technology User must promptly disclose to Monsanto any improvement or development it may discover or devise in relation to the INGARD Gene Technology and allow Monsanto to use, license or assign, without charge or restriction, any such improvement or development.

5. CONFIDENTIALITY OF MONSANTO INFORMATION

- 5.1 Monsanto will provide to the INGARD Technology User such information as is reasonably necessary for the purpose of the INGARD Technology User's compliance with government requirements in relation to this Agreement.
- 5.2 Any information which is communicated to the INGARD Technology User pursuant to clause 5.1 or any other information confidential to Monsanto otherwise communicated under this Agreement (individually and collectively referred to as the "Information") must be treated by the INGARD Technology User as confidential and must not be disclosed to any other person or corporation. This provision will not apply to the extent that:
 - (a) the INGARD Technology User has the written consent of Monsanto to disclose the Information; or
 - (b) the Information is or has been otherwise legally acquired by the INGARD Technology User from a third party (other than an INGARD Technology Service Provider) not in breach of any confidentiality obligation to Monsanto; or
 - (c) the Information is or comes into public domain or is or becomes generally known in the industry otherwise than by breach of this Agreement; or
 - (d) it is reasonably necessary for the INGARD Technology User to disclose their Information to its officers, directors and employees to enable those officers, directors and employees to perform their obligations in connection with the exercise of rights conferred by the License where those obligations are not inconsistent with the terms of this Agreement provided that the INGARD Technology User uses all reasonable endeavours to impose undertakings of confidentiality on those officers, directors, and employees to whom the Information was disclosed.
 - (e) The Information is required by any government instrumentality

If the INGARD Technology User is required to disclose the Information to a government instrumentality, all reasonable endeavours must be used by the INGARD Technology User to make disclosure under conditions of confidence.

5.3 The confidentiality obligations in clause 5.2 will survive the termination of this Agreement

6. FARM UNIT INFORMATION

- 6.1 Monsanto will not reveal any of the information acquired about the INGARD Technology User's Farm Unit as the result of this Agreement to any third parties except to the extent that Monsanto considers it necessary to disclose such information in order to:
 - (a) fulfil regulatory requirements;
 - (b) ensure compliance with this Agreement; or
 - (c) assist Cotton Seed Distributors Ltd. And DeltaPine Australia Pty. Ltd. To anticipate INGARD Cotton Seed demand

The information provided under this Agreement may be stored by Monsanto for a period of up to five years.

7. INGARD TECHNOLOGY USER'S LICENSE FEE

- 7.1 In consideration of the grant of the license, the INGARD Technology User hereby agrees to pay the Nominated TSP a fee (the 'License Fee')
- 7.2 In relation to each Farm Unit, the license Fee is AS185.00 per hectare of INGARD protection purchased by the INGARD Technology User pursuant to a Purchase Authority obtained in accordance with Clause 2.1(b)
- 7.3 The INGARD Technology User will be invoiced for the license Fee by the Nominate TSP on or about 14 December 1999.
- 7.4 Payment of the License Fee must be made by the INGARD Technology User to the Nominated TSP on or before 31 January 2000.
- 7.5 The INGARD Technology User acknowledges that should the INGARD Technology User fail to pay the license Fee in accordance with Clause 7.4, any and all Monsanto's rights to enforce the INGARD Technology User's obligations to pay may be enforced by the Nominated TSP as agent for Monsanto.

8. TERM

The term of this Agreement is for the period commencing on June 1, 1999 and ending on August 31, 2000 or when terminated by either party in accordance with clause 9 of this Agreement, whichever occurs first.

9. TERMINATION

- 9.1 If either party breaches any of the provisions of this Agreement, the other party may give notice to the first party of intent to terminate this Agreement specifying the alleged breach, and if the first party does not rectify that breach within 30 days after the service of that notice, the other party may terminate this Agreement forthwith by written notice to the first party.
- 9.2 Without limiting the generality of clause 9, the Agreement and all rights granted herein, will terminate on written notice from Monsanto to the INGARD Technology User in the event that:
- (a) any approval necessary for the due operation of this Agreement should be withdrawn; or
 - (b) effective control, by any means, of the INGARD Technology User is transferred to a person or corporation who does not have that control at the date of execution of this Agreement.

10. RIGHTS, DUTIES AND LIABILITIES UPON TERMINATION

- 10.1 Upon the termination of this Agreement, however caused, all rights and privileges of the INGARD Technology User under this Agreement will terminate.
- 10.2 Termination of this Agreement will have no effect by any means whatsoever upon any rights or liabilities which may arise from damages deriving from a breach of this Agreement prior to termination.

11. ASSIGNMENT

The INGARD Technology User may not assign any of its rights and/or liabilities pursuant to this Agreement without the prior written consent of Monsanto.

12. MISCELLANEOUS

- 12.1 This Agreement is governed by the laws in force in, and the parties submit to the non-exclusive jurisdiction of the courts of, the State of Victoria.
- 12.2 Any provision of this Agreement which is invalid or unenforceable in any jurisdiction will be ineffective in that jurisdiction to the extent only of such invalidity or unenforceability and will be severed from and will not invalidate the remaining provisions of this Agreement
- 12.3 The INGARD Technology User agrees that no failure or delay by Monsanto in exercising any right, power or privilege under this Agreement will operate as a bar thereof and no single or partial exercise thereof will preclude the exercise by Monsanto of any other right, power or privilege under this Agreement.
- 12.4 This Agreement may not be modified, amended or otherwise varied except by a document in writing signed by each of Monsanto and the INGARD Technology User (or an authorized representative thereof).

This Agreement supersedes all and any previous agreements whether oral or written in respect of the INGARD Gene Technology between the INGARD Technology User and Monsanto and any statement, disclosure, representation, warranty, condition, promise, undertaking or other provision not expressly set out in this Agreement has not been relied on and has no force or effect.

Attachment 4: OHIM Decision on the BOLLGARD trade mark**OFFICE FOR HARMONIZATION IN THE INTERNAL MARKET (TRADE MARKS & DESIGNS)****DECISION of the Third Board of Appeal of 21 October 1999** In Case R 266/1999-3

Monsanto Company
800 North Lindbergh Boulevard, St. Louis Missouri, USA
Applicant and Appellant

Ladas & Parry
52-54 High Holborn, London WC1V 6RR, United Kingdom
Representative

APPEAL relating to Community trade mark application number 549576

THE THIRD BOARD OF APPEAL

composed of S. Sandri (Chairman), Th. Margellos (Rapporteur) and A. Bender
Registrar: L. McGarry

gives the following **Decision**

Summary of the facts

1. By application filed on 2 June 1997 the applicant sought to register the word mark **BOLLGARD** for 'Insect-tolerant genes for use in agricultural seeds' in Class 1, 'Agricultural seeds containing insect-tolerant genes' in Class 31 and 'Cotton' in Class 22.
2. In a notice by fax of 3 December 1998, the examiner informed the applicant that the claimed trade mark did not appear to be eligible for registration under Article 7(1)(b) of Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (OJ EC No 11 of 14.1.1994, p. 1) (hereinafter 'CTMR'). In his view the mark consisted of two descriptive words, 'BOLL' referring to the fruit of flax and cotton consisting of a capsule containing seeds, and 'GUARD', meaning to watch over, shield, or protect from danger and harm, which when combined did not confer on the mark a distinctive character. The mark used in relation to the goods in the application was clearly descriptive since it indicated that they had been developed to protect the boll from disease or infestation.
3. By fax of 28 January 1999, the applicant replied stating that the claimed mark was not directly descriptive and that the combination of the elements 'BOLL' and 'GARD' was sufficiently original and therefore distinctive as a trade mark.
4. By decision of 29 March 1999 (hereinafter 'the contested decision'), the examiner informed the applicant that the application was not eligible for registration under Article 7(1)(b) CTMR. The examiner justified his decision as follows:

'The mark is considered devoid of distinctive character as it merely describes significant characteristics of the goods namely that they protect the boll of certain plants from infestation or disease or that they are resistant to infestation or disease. This impression is immediately obvious notwithstanding the slight misspelling of the word "guard" or the fact that the mark is a combination of two words. An analysis of the component elements of a mark may be made when assessing a mark's overall impression. ...In this particular case the mark indicates the nature of the products directly and immediately and is therefore considered to be primarily descriptive and devoid of distinctive character. ... A newly

coined word or expression can still be devoid of any distinctive character if it is perceived as merely describing significant characteristics of the goods applied for. ... *the fact that a trade mark is contrived, and as such is not found in a dictionary, does not preclude that mark from being descriptive* [decision of 8 July 1998 in Case R 29/1998-3 – ENAMELIZE].

5. On 14 May 1999, the applicant filed a notice of appeal against the contested decision. The statement of the grounds of appeal was received on 23 July 1999.

6. Its arguments may be summarised as follows:

1. The combination of the words 'BOLL' and 'GARD', creates a word which does not exist in any dictionary in any language of the Community and is sufficiently novel and inventive as to give a limited degree of distinctiveness.

2. The mark is merely suggestive and is not directly descriptive, and no trader would wish to make use of this combination.

3. Registrations of the claimed mark in Spain and Greece for products in Classes 1 and 31 are an indication that absolute grounds for refusal are unlikely to exist and should be taken into account.

7. The appeal was submitted to the examiner for interlocutory revision pursuant to Article 60 CTMR on 26 July 1999. The Examination Division did not grant interlocutory revision and remitted the appeal to the Board on 3 August 1999.

8. Reference is made to the documents in the file including, in particular, the pleadings of the appellant, which have been considered by the Board and taken as a basis for its decision.

Reasons

9. The appeal complies with Articles 57, 58 and 59 CTMR and Rule 48(1) of Commission Regulation (EC) No 2868/95 of 13 December 1995 implementing the CTMR (OJ EC L 303 15.12.1995, p. 1). It is therefore admissible.

10. The issue to be decided is whether in the light of Article 7(1)(b) and (c) CTMR, the trade mark 'BOLLGARD' should be refused registration for the goods in the application. In that regard, an examination on absolute grounds must focus on the overall visual, aural and conceptual impression created by the mark, taking into account the presumed expectations of the average consumer, who is reasonably well informed and reasonably observant and circumspect.

11. Pursuant to Article 7(1)(b) CTMR, a trade mark which is devoid of any distinctive character, namely, one that is not capable of distinguishing the goods of one undertaking from those of another, cannot be registered. The essential function of a trade mark is to guarantee to the consumer the identity of the origin of the marked product, i.e. that all goods and services bearing it have originated from under the control of a single undertaking responsible for its quality (see judgment of the Court of Justice in Case C-39/97 *Canon Kabushiki Kaisha v Metro-Goldwyn-Mayer Inc* [1998] ECR I-5507, paragraph 28). A trade mark must, therefore, be distinctive and be capable of serving as an indication of origin (see judgment of the Court of First Instance of 8 July 1999 in Case T-163/98 *The Procter and Gamble Company v OHIM*, paragraph 21).

12. Pursuant to Article 7 (1)(c) CTMR, 'trade marks which consist exclusively of indications which may serve, in trade, to designate the kind, quality, intended purpose... or other characteristics of the goods cannot be registered'. They must remain available for general use, since competitors have a legitimate interest in employing, without hindrance, in a descriptive manner

such indications relating to the very nature of the claimed goods.

13. An objection under Article 7 (1)(c) CTMR may, however, only be maintained where the descriptive content is immediately, clearly and unmistakably obvious from the application, particularly since experience shows that customers are unlikely to engage in a conceptual analysis of the trade marks they encounter in order to read descriptive meanings into them. It is more usual for consumers to accept trade marks, without much forethought being given, as they appear on the market. If a term that could serve to describe the characteristics of goods is merely hinted at and is recognisable only on the basis of intellectual conclusions, it does not usually impede the registration (see decision of 26 February 1999 in Case R 71/1998-3 – PORTFOLIO, paragraph 10).

14. According to *Textile Terms and Definitions*, Tenth Edition, The Textile Institute, 1995, the word 'BOLL' refers to 'a seed-case and its contents on the cotton plant'. According to *A Dictionary of Natural Products* by George Macdonald Hocking, PH.D, Plexus 1997, the term 'BOLL' refers to a 'rounded capsule of cotton, flax'. The second element 'GARD' however has no dictionary meaning.

15. The Board considers that the claimed mark considered as a whole is unusual and sufficiently inventive since it is a combination of an arbitrary, imaginative and inventive element with another word, albeit descriptive. There is therefore no reason to hold that it is not capable of distinguishing the appellant's products from those of other undertakings, or that any undertaking should be reserved the right to use it in relation to competing products. Accordingly, it has a sufficient degree of minimal distinctiveness in order to be eligible for registration pursuant to Article 7(1)(b) CTMR.

16. Furthermore, the merger of the two elements in the claimed mark is not descriptive of any characteristic under Article 7(1)(c) CTMR. The term 'BOLLGARD' has no commercial meaning and would not obviously and immediately be taken as descriptive of any characteristic of the goods in the application. Nor would the registration of 'BOLLGARD' as a trade mark prevent the appellant's competitors from claiming that their goods are resistant to disease or infestation.

17. In addition, since the element 'GARD' is invented and is visually distinguishable from the word 'guard', the Board is not convinced that the relevant user would pronounce it in the same way as the word 'guard'. Nor would he automatically assume that the word 'gard' was a phonetic equivalent of the word 'guard'. Rather, he would make an association with the latter word only after forethought. Accordingly, the Board considers that the relevant user confronted with the claimed mark used in connection with the products in the application will not have an immediate and precise idea that the products in the application will shield flax or cotton plants from disease or infestation. It is therefore not descriptive of the intended purpose of the products in the application under Article 7(1)(c) CTMR.

18. For the foregoing reasons, the contested decision must be set aside and the case is remitted to the examiner for further prosecution.

Order

For those reasons, it is decided that:

The decision of 29 March 1999 is set aside and the case is remitted to the examiner for further prosecution.

S. Sandri Th. Margellos A. Bender

Registrar: L. McGarry