

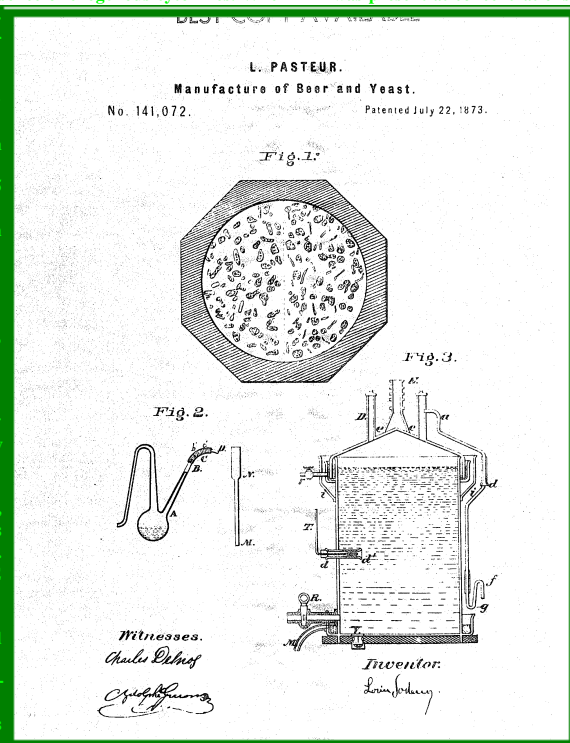
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purified and cultured as described in Example 14 above. In or the purified B cells (1.times.10.sup.5 cells/well) were grown Laboratodes, Detroit, Mich.) and three-fold dilutions of IL-4 555 ng/ml or medium control (.DELTA.) (see FIGS. 8A-8C 750.times.g and culture supernatant fluids were harv specific sandwich ELISA technique as follows. 96-well flat-b with the appropriate (see below) first step isotype specific ant phosphate buffered saline containing 0.05% Tween 20, 6 rins 5% nonfat dry milk. Test material (100 ul), either cu in PBS/3% BSA), was added to each well, for 1 hour, then w:

## Intellectual Property and Biotechnology: A Training Handbook

l of the appropriate (see below) horseradish peroxidase-conjugated second step antibody was added and plates were incubated for 1 hour and washed. The presence of peroxidase-ody was determined by using the TMB peroxidase substrate system Perry Laboratories, Inc., Gaithersburg, Md.). Plates were read on a Dynatech ELISA bu the reader. Immunoglo trations in test samples were determined by comparing triplicate test values with isotype control standard curves, using the DeltaSoft 1.8 ELISA analysis program for the Mad etallics, Inc., Princeton, N.J.). For the IgG1 and IgG3 assays, unconjugated and horseradish peroxidase-conjugated affinity purified goat anti-mouse isotype specific reagents (Sou hngology Associates, Inc., as plate coating and second tively. Standard curves for isotype matched murine erno). For the IgE assay, the iAb (Baniyash et al., Eur. J. ded by Dr. Fred Finkelman, ida, Md.) was used as plate ylated rat anti-mouse IgE ndianapolis, Ind.) was used as radish peroxidase-conjugated in the third step. Standard r murine anti-dinitrophenol specific Ige myeloma antibody (ATCC No. TIB 141). All three ELISA assays were determined to be specific based upon cross-reactivity experiments u dual murine antibody isotypes as controls. The effect of various doses of inhibitor on the inhibition of IgG1, IgG3 and IgE secretion is shown in FIGS. 9A-9C. In this experiment, purified l es.10.sup.5 cells/well) were grown in 96-well flat bottom plates in the presence of Salmonella typhimurium LPS (Difco Laboratories, Detroit, Mich.) and IL-4 (30 ng/ml for IgE; 3 ng/ml for gG3) in the presence of three-fold dilutions of sIL-4R (.quadrature.), sIL-1R (.box-solid.) or 11B11 (.circle-solid.). Six days after initiation of culture, cells were pelleted by centrifugati nes.g and culture supernatant fluids were harvested. The supernatants were analyzed for IgG1, IgG3 and IgE secretion using the isotype specific sandwich ELISA technique described a 8A and 8B show that IgG1 and IgE secretion from LPS treated B cells was induced by IL-4 and that these activities were inhibited by both the sIL-4R as well as 11B11. In contrast, FI that IgG3 secretion was induced by LPS directly in the absence of exogenous cytokines. When IL-4 was present at concentrations of 10 ng/ml or less, LPS induced IgG3 secretion was ab R blocked this inhibitory effect of IL-4, shifting the IL-4 secretion in the presence of otherwise inhibitory doses of IL-4 switching by sIL-4R was dose dependent: with increasing and IgE and Inhibition of IL-4 Induced Immunoglobulin ion of IgG1 and IgE and inhibits IgG3 production, possibly antibody to another isotype. The ability of sIL-4R to inhibit in the following assay that measures immunoglobulin ultured as described in Example 14 above. In order to IgG3 secretion, the purified B cells (1.times.10.sup.5 ce of Salmonella typhimurium LPS (Difco Laboratodes, irature.), sIL-1R (.boxsolid.) or 11B11 (.circle-solid.), each six days after initiation of culture, cells were pelleted by harvested. Immunoglobulin (IgG1, IgG3, and IgE) levels que as follows. 96-well flat-bottom Linbro plates (Flow ppropriate (see below) first step isotype specific antibody done with phosphate buffered saline containing 0.05% ubation for one hour with 150 ul of 5% nonfat dry milk. rd curve solutions (all sample and antibody dilutions in washed. 100 ul of the appropriate (see below) horseradish wee incubated for 1 hour and washed. The presence of iB Microwell peroxidase substrate systKirkegaard & Perry atech ELISA reader. Immunoglobulin concentrations in with isotype control standard curves, using the DeltaSoft Princeton, N.J.). For the IgG1 and IgG3 assays, y purified goat anti-mouse isotype specific reagents used as plate coating and second step reagents, respectively. hed murine myeloma pro proteins (Southern). For the IgE Eur. J. Immunol. 14:797, 1984) (provided by Dr. Fred coating step reagent and biotinylated rat anti-mouse IgE ond step reagent, and horse radish peroxidase-conjugated s; were established with a murine anti-dinitrophenol specific A assays were determined to be specific based upon cross es as controls. The effect of various doses of inhibitor on



Birmingham, Ala.) step rea IgG1 and IgG3 wer myeloma pr EM95 IgG2a anti- Immunol. 14:797, Uniformed Ser coating step reagen (Bioproducts for Sc second step reagent streptavidin (Zymec curves were estab usal murine anti-dinitrophenol specific Ige myeloma antibody (ATCC No. TIB 141). All three ELISA assays were determined to be specific based upon cross-reactivity experiments u dual murine antibody isotypes as controls. The effect of various doses of inhibitor on the inhibition of IgG1, IgG3 and IgE secretion is shown in FIGS. 9A-9C. In this experiment, purified l es.10.sup.5 cells/well) were grown in 96-well flat bottom plates in the presence of Salmonella typhimurium LPS (Difco Laboratories, Detroit, Mich.) and IL-4 (30 ng/ml for IgE; 3 ng/ml for gG3) in the presence of three-fold dilutions of sIL-4R (.quadrature.), sIL-1R (.box-solid.) or 11B11 (.circle-solid.). Six days after initiation of culture, cells were pelleted by centrifugati nes.g and culture supernatant fluids were harvested. The supernatants were analyzed for IgG1, IgG3 and IgE secretion using the isotype specific sandwich ELISA technique described a 8A and 8B show that IgG1 and IgE secretion from LPS treated B cells was induced by IL-4 and that these activities were inhibited by both the sIL-4R as well as 11B11. In contrast, FI that IgG3 secretion was induced by LPS directly in the absence of exogenous cytokines. When IL-4 was present at concentrations of 10 ng/ml or less, LPS induced IgG3 secretion was ab R blocked this inhibitory effect of IL-4, shifting the IL-4 secretion in the presence of otherwise inhibitory doses of IL-4 switching by sIL-4R was dose dependent: with increasing and IgE and Inhibition of IL-4 Induced Immunoglobulin ion of IgG1 and IgE and inhibits IgG3 production, possibly antibody to another isotype. The ability of sIL-4R to inhibit in the following assay that measures immunoglobulin ultured as described in Example 14 above. In order to IgG3 secretion, the purified B cells (1.times.10.sup.5 ce of Salmonella typhimurium LPS (Difco Laboratodes, irature.), sIL-1R (.boxsolid.) or 11B11 (.circle-solid.), each six days after initiation of culture, cells were pelleted by harvested. Immunoglobulin (IgG1, IgG3, and IgE) levels que as follows. 96-well flat-bottom Linbro plates (Flow ppropriate (see below) first step isotype specific antibody done with phosphate buffered saline containing 0.05% ubation for one hour with 150 ul of 5% nonfat dry milk. rd curve solutions (all sample and antibody dilutions in washed. 100 ul of the appropriate (see below) horseradish wee incubated for 1 hour and washed. The presence of iB Microwell peroxidase substrate systKirkegaard & Perry atech ELISA reader. Immunoglobulin concentrations in with isotype control standard curves, using the DeltaSoft Princeton, N.J.). For the IgG1 and IgG3 assays, y purified goat anti-mouse isotype specific reagents used as plate coating and second step reagents, respectively. hed murine myeloma pro proteins (Southern). For the IgE Eur. J. Immunol. 14:797, 1984) (provided by Dr. Fred coating step reagent and biotinylated rat anti-mouse IgE ond step reagent, and horse radish peroxidase-conjugated s; were established with a murine anti-dinitrophenol specific A assays were determined to be specific based upon cross es as controls. The effect of various doses of inhibitor on

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**A training resource for developing countries in the APEC region funded under the APEC Support Program of the Australian Agency for International Development (AusAID) December 2001**



**FOREIGN AFFAIRS AND TRADE**



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## Acknowledgements

This handbook was partly funded by the Australian Agency for International Development (AusAID) under the APEC Support Program, within a project administered by the Australian Department of Foreign Affairs and Trade (DFAT). It aims to supplement and promote the valuable cooperation undertaken by the APEC Intellectual Property Rights Experts' Group.

IP Australia and the Plant Breeders' Rights Office provided considerable support and guidance in the course of this program, and their assistance is warmly appreciated. This handbook does not embody or endorse any formal policy position on the part of any of its contributors, and does not represent the official views of the Australian Government or any of its agencies.

This handbook builds on training programs conducted in Melbourne, Hanoi, Bangkok, Beijing, Jakarta, Padang and Solo from 1998 to 2001. We acknowledge with warm gratitude the valuable support, input and involvement of the following people who made various contributions to the conduct of the training programs or in the preparation of this handbook. Any errors and omissions in this handbook are, however, wholly the responsibility of the editors.

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Mr Antony Taubman, Australian National University  
Dr Cassandra Thumwood, Ludwig Institute  
Dr Lyndal Thorburn, Advance Consulting  
Professor Geoffrey Tregear, Howard Florey Institute  
Mr Leigh Tristram, IP Australia  
Mr Doug Waterhouse, Plant Breeders' Rights Australia

The many participants in these programs have also provided invaluable input, and this is acknowledged with gratitude. We thank AMRAD for its support for the training program. We also thank *New Scientist*, Dr. Niall, and *Signals* for their permission to reproduce extracts from their publications in *Module Six* and *Module Nine*, *Nine*, and Monsanto Australia for the use of the INGARD Technology User Agreement in *Module Ten*.  
The principal author of this publication is Antony Taubman.

## PLEASE NOTE

**This handbook is designed to provide a practical introduction to the nature and management of intellectual property rights in relation to biotechnology. It is intended to contribute material for use in training courses, to assist in raising awareness of some of the complex issues that surround the protection and management of intellectual property in the field of biotechnology, and to assist in the development of practical skills.**

**The handbook does not seek to provide legal, managerial or technical advice on intellectual property law. It should in no way be considered a substitute for expert legal, technical and managerial advice. You should seek qualified professional advice on any aspect of intellectual property law and management, and should not rely on this handbook.**

**This handbook does not expressly represent the official view of the Australian Government or any of its agencies, and is not intended to sanction or advocate any particular policy position or viewpoint.**

**We have endeavoured to ensure that the contents of this handbook are accurate and correct, but there may be errors or omissions. Kindly advise of any errors, inaccuracies or significant omissions to the address below so they can be rectified in later versions.**

**Comments and suggestions as to how the handbook could be usefully enhanced or extended would also be gratefully received.**

An on-line version of this handbook, with any updates and amendments, will be available at <http://www.dfat.gov.au/ip>

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## How to use this handbook

### ***Who is this handbook for?***

This handbook does not assume any background in intellectual property law or in biotechnology. It is aimed at a general audience, including scientific researchers, public research institutions, commercial research institutions, businesspeople, industry associations, academics, lawyers, policy makers, officials in government intellectual property offices and individuals with an interest in biotechnology and intellectual property. Part Two, on managing intellectual property, is written mostly from the perspective of researchers in public sector institutions and universities, but should be of interest to other groups as well.

### ***What is the aim of the handbook?***

The handbook does not attempt to provide advanced technical training in the complex field of intellectual property and biotechnology. It does aim at giving an overview of the key concepts and the legal framework, and a practical understanding of how they are applied in practice. It is therefore intended to provide basic tools for using the IP system and to lay the groundwork for further study and research.

### ***Using the handbook***

This handbook is designed with ten self-contained modules. It can be used:

- for an intensive specialist training course, which covers all the modules at once; or
- for specific training on one particular topic (e.g. using patent information or plant breeder's rights), when you can pick and choose which modules to do accordingly.

The modular structure of the handbook is intended to ensure it can be used flexibly. This means there is some overlap in subject matter between modules, but this has been found helpful in consolidating understanding when undertaking longer training courses.

The handbook can be used for individual or group training. It was created and tested as a resource for group training activities ranging from two days to two weeks. The exercises are therefore written with the needs of a group in mind, particularly the major exercises on patent law in *Module Five* and *Module Six*. To be run as planned, the major group exercises will need some advance organisation (including the availability of facilitators if possible), and preparation of the individual bundles of documents for each distinct group. Individual users of the handbook can work through the group exercises considering the perspective of each separate interest group represented in each case.

Each module follows the same format. The objectives for each module are set out at the beginning so that you know which are the most important points for you to focus on. Most modules include examples to help you understand the issues discussed. Each module also concludes with a summary. Each module has a set of group exercises. These are not intended for assessment purposes, but rather to stimulate group discussion about the issues raised, and to give some practical experience in applying the information and skills covered in the module. Individual users of the handbook can also use these exercises to check whether they have understood the material covered in the module before moving on.



## Overview

### ***Introduction***

Biotechnology in one form or another has been part of human development since the dawn of agriculture. Human ingenuity has led to increased production and greater diversity and quality of livestock and varieties of crops. Today's food crops and domestic animals embody the benefits of many generations of selection and breeding.

Biotechnology continues to offer considerable potential for enhancing human health and well-being. Modern biotechnology, including gene technology, is finding increasing application in healthcare and in a host of industrial and agricultural industries. Effectively applied, modern biotechnology may contribute to economic growth, technological development and human welfare. Yet it has also raised concerns about ethical and moral issues, equitable sharing of the benefits of biotechnology, environmental impact, the accelerated pace of change and the regulatory challenges. Intellectual property (IP) rights are not new in the biotechnology domain, but some of the concerns about modern biotechnology have focussed on the nature, impact and legitimacy of IP rights as they are applied to gene technology and to inventions that draw on genetic resources and associated traditional knowledge.

Just as the impact of modern biotechnology is beginning to be felt, there is increasing recognition of the importance of a balanced IP system in assuring economic development. Many countries are currently building IP issues into their economic, industrial and technological planning, and into research and education programs. This leads to a debate about balancing public and private interests - on the one hand, providing sufficient incentives for the investments required to bring new technologies to the public, and on the other ensuring that there is sufficient flexibility and capacity for ensuring that the benefits of new technologies are widely available on equitable terms. In relation to biotechnology, there are also concerns that IP rights do not encompass material in the public domain or that has been somehow misappropriated. The important debate on how best to achieve this balance is continuing at national and international levels: this handbook does not seek to advance any particular point in this policy discussion, and focusses instead on describing the current system with reference to general international standards.

There is no doubt that reaping the social benefits and potential value of IP, however the overall balance of interests is struck, does require a practical understanding of how the IP system operates and how IP rights can be used and managed most effectively. This handbook concentrates on this area of awareness and expertise, in the hope that it will assist in the more effective use of the IP system to achieve the positive outcomes that are hoped for. It aims to encourage a view of the IP system as more than an inert collection of legal documents, so that it becomes a toolkit for development of and access to technologies, and a means of ensuring their beneficial application. Not all researchers need to become patent experts, but many are under pressure to make better use of the IP system to assist in ensuring that their research outcomes can be effectively disseminated and used, and often to ensure improved funding for future research programs. This handbook is intended to make a modest contribution to fulfilling these needs.

### ***The scope of the handbook***

The handbook aims to cover the following general topics:

- the range and different types of IP rights,
- the international framework for the protection of IP,
- how patent law protects biotechnology inventions,
- the legal requirements and administrative steps for getting a patent,
- how databases of technical and patent information can help in research,
- how to search databases for technical and patent information,
- how to read, interpret and assess the effect of a patent document,
- the nature of plant breeder's rights systems,
- IP as a factor in a research and development,
- how to negotiate research contracts with commercial partners, and
- the management and practical use of IP rights, including licensing and enforcement.

### **STRUCTURE AND CONTENTS**

Part One of the handbook – 'Intellectual Property Law' - focusses on the principles and key features of intellectual property (IP) law, with particular reference to biotechnology IP. It provides an introduction to patents and the use of patent documentation as source of technological information, and has two extended group exercises which allow for in depth application and discussion of the principles of patent law. It also covers separate systems for plant variety protection. Part Two – 'Using Intellectual Property' - then looks at how IP rights are used in practice to achieve benefits such as commercialisation of research, access to technology and the dissemination to the public of new technologies. It concludes with case studies on the use of IP rights in bringing new technologies to the market.

#### **Module One: Introduction to Intellectual Property**

This provides an overview of the chief forms of IP rights potentially relevant to biotechnology – patents, plant breeders rights, confidential information (or trade secrets), trade marks and geographical indications. It covers some of the key international agreements on IP and some of the principles they give effect to. It also briefly reviews some of the reasons put forward for protecting IP, and some criticisms of the IP system.

#### **Module Two: Biotechnology and Intellectual Property**

This module goes into more detail about IP as it applies to biotechnology, with a particular concentration on patents and the principles of patent law – looking particularly at the nature of a patent right, and the tests an invention must pass to be eligible for a patent. The module's exercises include looking at two patents that have been the subject of much international debate, one concerning turmeric and one on rice.

#### **Module Three: Reading a Biotechnology Patent and the Patent Process**

This module considers the details of the patent system, looking at the contents of patent documents, the interpretation of patent claims, and the processes that lead to a patent, including the international system known as the PCT (Patent Cooperation Treaty).

#### **Module Four: Searching Patent Databases**

This module considers one of the key practical uses of the patent system, its role as a source of technological information and information on rights that may affect research and development programs. It covers the practical skills that are needed to access patent information, and how it can be used to avoid 'reinventing the wheel,' to monitor emerging technologies, and to avoid conflict with existing rights.

#### **Module Five: Group Exercise on Patent Validity: Neem**

This exercise gives practical exposure to preparing, analysing and opposing a patent application in a relatively simple field of technology (although one that raises strong concerns about the use of genetic resources and traditional knowledge), and considering legal criteria such as novelty and inventiveness, as well as exclusions on patentability. Ideally, it should be run with participants organised in four groups, each group playing a particular role in relation to the patent.

#### **Module Six: Group Exercise on Patent Validity: Relaxin**

This exercise looks in more detail at key legal principles such as inventiveness and exclusions from patent rights on moral grounds, and applies them to a more complex biotechnology patent involving DNA sequences. This exercise is also organised to be run with four groups. Because of the complexity of the technology, it is preferable to use facilitators and to circulate the relevant documents well in advance of the exercise.

#### **Module Seven: Plant Breeders' Rights**

This module describes the separate system of protection for plant varieties, often termed plant breeders' rights. It contrasts these rights with the patent system, and sets out the international framework for plant variety protection.

#### **Module Eight: Researching and Intellectual Property Rights**

This module considers the practical needs of a researcher and considers the various ways the IP system affects research and development – such as research agreements, confidentiality agreements, laboratory notebooks, and the negotiation of freedom to operate in relation to other IP rights.

#### **Module Nine: Licensing and Enforcing Intellectual Property Rights**

This module considers what happens after research has been successfully concluded, and it comes to put the product on the market. What options are there for licensing IP and otherwise commercialising or disseminating research, and how are IP rights enforced? The module considers the issues raised in license negotiation, such as ownership and validity of IP rights, royalty rates, territory, exclusivity, allocation of costs and responsibilities for maintaining and enforcing IP rights, confidentiality and publication issues, insurance, release and indemnity and dispute resolution and termination.

#### **Module Ten: Case Studies on Commercialising Research**

This module discusses general issues arising from the increasing pressure on research institutes to commercialise their work. It then considers an hypothetical case of negotiations on freedom to operate in relation to existing IP rights, and describes the path to commercialisation in Australia of Bt cotton, the first transgenic crop approved for commercial release.