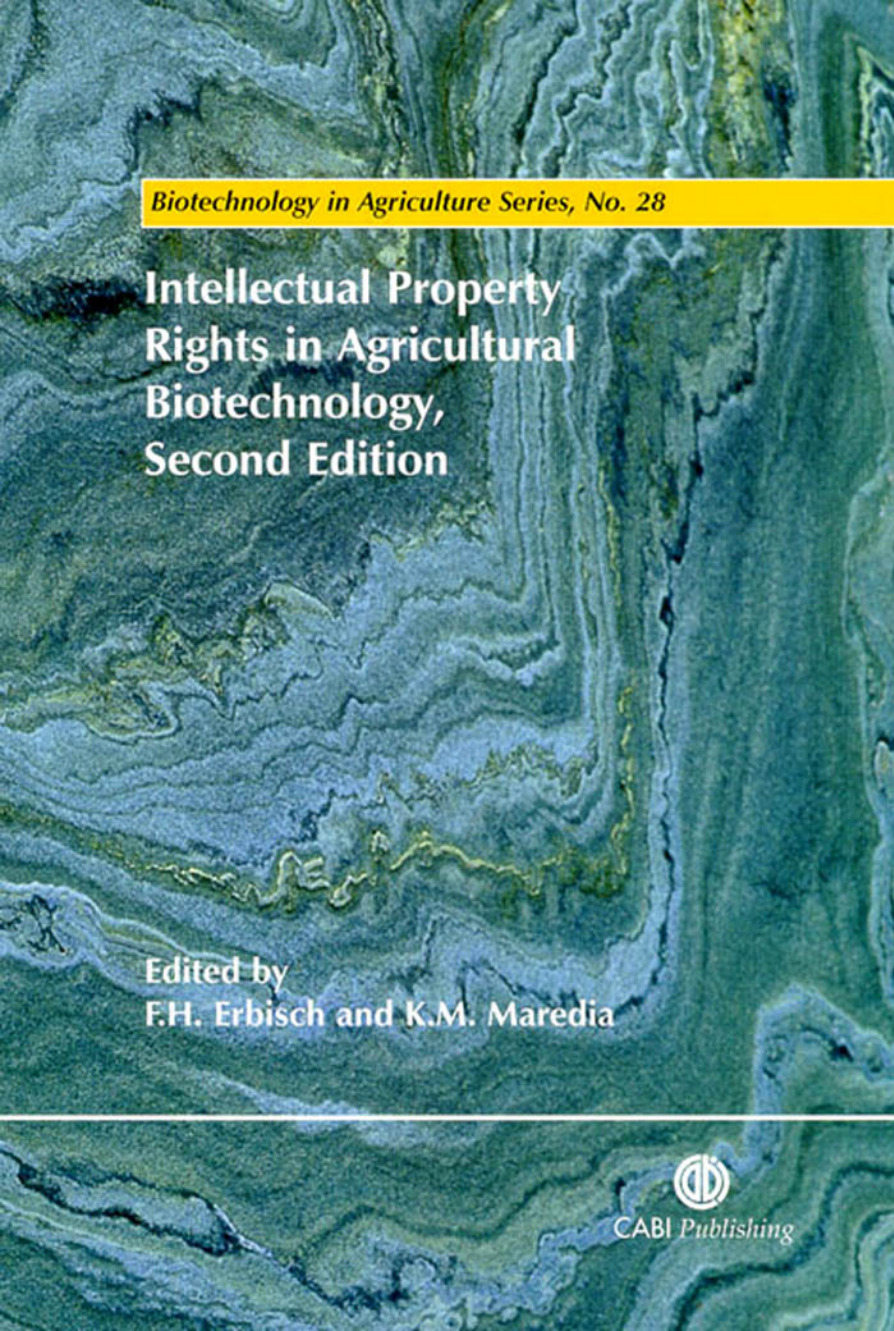
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Edited by
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I. Gordon
28: Intellectual Property Rights in Agricultural Biotechnology, 2nd edition
F.H. Erbisch and K.M. Maredia

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Intellectual Property Rights in Agricultural Biotechnology

Second Edition

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Preface to the Second Edition

The first edition of this book, published in 1998, according to reviews and comments from others, fulfilled a need in the international community that was just beginning to learn the significance of intellectual property management. We used the handbook as the basic text in the internship programme we held at Michigan State University. In addition, the book has been used in a number of other intellectual property management internship programmes held at Michigan State University and elsewhere.

Individually we used the handbook in seminars and other programmes we were involved with in developing countries throughout Africa, Asia, Central America and South America. As we were working with individuals from around the world it became evident that the intellectual property scene was rapidly changing and the 'Country and Regional Case Studies' section of the handbook was becoming very dated. The developing countries we were interacting with were passing new legislation and enacting new laws, thereby changing the face of the intellectual property scene and making many of these chapters outdated. These countries were striving to become TRIPS compliant. It became very obvious to us that the book needed to be updated. Also, we had received a number of suggestions for including more in the first section of the handbook, 'Issues and Principles'. CAB International's approval of our proposal for a second edition was granted and we began to rebuild the handbook.

In the first section of the second edition of the book we have added a chapter dedicated to plant variety protection, another chapter to cover the economic implications of intellectual property management and a

third chapter on farmers' rights. This latter chapter provides a background on the role of policies and treaties on farmers' rights, as well as looking forward to providing a view of how farmers' rights might be handled in the future.

In the second section we have added three new country chapters, Indonesia, Russia and Brazil, as well as having other country chapters updated. Although we asked the authors of these case history chapters to limit their endeavours to a certain number of pages, several were unable to do so. So many changes had occurred in the intellectual property scene in their countries that they needed additional space. Their requests were granted and the reader will now find several 'extended' country chapters. We anticipate that the steps these countries have taken will provide further guidance for other countries as they take steps to review and build their national intellectual property protection programmes. We also hope that readers will contact the authors of the various chapters to learn in more detail the steps that were taken to reach the status they now have attained.

It is our expectation that this edition of the handbook will be as important as was the first in providing information on intellectual property management concepts and practical implementation to those needing such guidance. If, through this book, we have helped you or your country, we are especially pleased.

The opinions expressed by the chapter authors in this book are not necessarily those of the editors.

Preface to the First Edition

In 1991 Michigan State University entered into a multi-year cooperative agreement with the US Agency for International Development. The objective of the award was, with the assistance of other universities and private industry, to develop research relationships with emerging countries to train their scientists effectively to utilize biotechnology in enhancing plant agricultural products. The project was called the Agricultural Biotechnology for Sustainable Productivity (ABSP) programme. The cooperative research effort proved to be beneficial for all parties. However, it was realized that two non-research policy areas needed to be addressed before the full benefit of the research programme could be gained. These policy areas were intellectual property rights and biosafety. Workshops and training programmes for both areas were developed by ABSP. Intellectual property workshops were held in the USA, Egypt, Indonesia and Morocco. The responses to these workshops were very positive and, as a result, Michigan State University, with the assistance of ABSP, designed and conducted two intellectual property internship programmes at its East Lansing, Michigan, campus. Over 500 individuals, including scientists, attorneys, government officials and other agricultural personnel, from more than 15 emerging countries, participated in these workshops and internship programmes. Participants at these workshops and internship programmes often asked about the availability of printed material or a handbook containing the basic materials taught in the programme. They wanted to share this with others who they believed would benefit from this material. While handouts were provided, they did not satisfy these requests. Nothing satisfactory was found in published literature, so it was decided to draft a book

which would meet the needs of the participants of the workshops and internships. The result is this book. It contains basic information about intellectual property, including its protection and marketing. Special efforts were taken to make the book definitive, yet to minimize the legal jargon which is found in so many published works on intellectual property. Finally, individuals from around the world were asked to provide a summary of intellectual property management in their country or region. The material provided by these authors illustrates the developmental stage of intellectual property programmes, laws and legislation in their geographic regions. It is hoped this material can provide direction, and perhaps assistance, to those countries developing their own intellectual property programmes.

Acknowledgements

The editors would first like to thank CAB International for publishing this handbook. Without their patience and expertise, this publication would not have been possible. The Institute of International Agriculture at Michigan State University and its support staff were also very helpful. We especially want to thank Dr Daniel Clay, Director of the Institute, for his understanding and special support of this book. We also want to thank Ms Pat Sutherland for her assistance in formatting the manuscripts and Ms Cathy Pisano for her efforts in keeping everything in order. For those of you who have shared your expertise with us and presented it in a way that all can understand, we thank you so very much. Special thanks go to all the international contributors for providing insight to the current status of intellectual property rights in their countries or regions. Thanks to all those who have encouraged us to develop this second edition, who said that there have been so many changes in intellectual property happenings since 1998 that you must include them in another edition of the handbook. It is difficult to describe the monumental efforts required to develop this handbook, so we must also thank our wives for their understanding as we went about our daily jobs and also worked on the handbook. Thanks to you all.

Frederic H. Erbisch
Karim M. Maredia

Acronyms and Abbreviations

AARD	Agency for Agriculture Research and Development (Indonesia)
ABSP	Agricultural Biotechnology Support Project
AGERI	Agricultural Genetic Engineering Research Institute (Egypt)
AIC	Administration for Industry and Commerce (People's Republic of China)
AIPPI	Association Internationale pour la Protection de la Propriètè Industriella
APEC	Asia Pacific Economic Cooperation
ARC	Agricultural Research Council (South Africa)
ARIPO	African Regional Industrial Property Organization
ASTA	American Seed Trade Association
AUTM	Association of University Technology Managers
BIO	Biotechnology Industry Organization
BIRPI	United International Bureaux for the Protection of Intellectual Property
BST	bovine somatotropin
CBD	Convention on Biological Diversity
CCPA	Court of Customs and Patent Appeals (USA)
CDA	confidential disclosure agreement
CGIAR	Consultative Group on International Agricultural Research
CIPRO	Companies and Intellectual Property Registration Office (South Africa)
CITES	Convention on International Trade in Endangered Species

CNPq	National Research Council (Brazil)
CRF	Code of Federal Regulations (USA)
CRIFC	Central Research Institute for Food Crops (Indonesia)
DUS	distinct, uniform and stable
EC	European Community
EDV	essentially derived variety
EMR	exclusive marketing rights (India)
EPA	Environmental Protection Agency (USA)
EPC	European Patent Convention
EPO	European Patent Office
ETF	enforcement task force
EU	European Union
FAO	Food and Agriculture Organization (UN)
FDA	Food and Drug Administration (USA)
FIE	Foreign Investment Enterprise (People's Republic of China)
FTAA	Free Trading Area of the Americas (Brazil) (also ALCA)
GATT	General Agreement on Tariffs and Trade
GMO	genetically modified organism
GPA	global plan of action
IKS	indigenous knowledge system
INPADOC	International Patent Documentation Centre
INPI	National Institute of Industrial Property (Brazil)
IP	intellectual property
IPR	intellectual property rights
JPO	Japanese Patent Office
KIAT	Kekayaan Intellectual dan Alich Teknologi (Indonesia)
M&A	merger and acquisition
MCI	Ministry of Chemical Industry (People's Republic of China)
METI	Ministry of Economics, Trade and Industry (Japan)
MEXT	Ministry of Education, Culture, Sports Science and Technology (Japan)
MOFTEC	Ministry of Foreign Trade and Economic Cooperation (People's Republic of China)
MSU	Michigan State University
MTA	material transfer agreement
NAFTA	North American Free Trade Agreement
NARI	National Agricultural Research Institute
NARS	National Agricultural Research Systems
NBA	National Biodiversity Authority (India)
NCA	National Copyright Administration (People's Republic of China)
NCGRP	National Center for Genetic Resources Preservation
NDUS	novel, distinct, uniform and stable

NGO	non-governmental organization
NIC	newly industrializing country
NIEO	new international economic order
NTB	non-tariff barriers
OAPI	Organisation Africaine de la Propriété Intellectuelle
OECD	Organization for Economic Cooperation and Development
OIP	Office of Intellectual Property
OTA	Office of Technology Assessment (USA)
PBR	plant breeders' rights
PCT	Patent Cooperation Treaty
PGR	plant genetic resources
PGRFA	plant genetic resources for food and agriculture
PPA	Plant Patent Act (USA)
PRC	People's Republic of China
PTO	Patent and Trademark Office (USA)
PVP	plant variety protection
PVPA	Plant Variety Protection Act (USA)
PVPO	Plant Variety Protection Office
PVR	plant variety right
R&D	research and development
RIFCB	Research Institute for Food Crops Biotechnology in Indonesia
SAGENE	South African Committee for Genetic Experimentation
SAIC	State Administration for Industry and Commerce (People's Republic of China)
SANSOR	South African National Seed Organization
SARIMA	South African Research and Innovation Managers' Association
SNPC	Cultivar Protection Office (Brazil)
SPC	State Planning Commission (People's Republic of China)
TLO	technology licensing office
TNC	transnational corporation
TPD	Transvaal Provincial Division
TRIPS	Trade-related Aspects of Intellectual Property Rights
TTO	technology transfer office
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNCTAD	United Nations Conference on Trade and Development
UNCTC	United Nations Centre for Transnational Corporations
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization

UNIDO	United Nations Industrial Development Organization
UNU-INTECH	United Nations University Institute for New Technology
UPOV	Union Internationale pour la Protection des Obtentions Végétales or International Union for the Protection of New Varieties of Plants
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USTR	United States Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization (UN)
WTO	World Trade Organization

1

Introduction to Intellectual Property

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Introduction

Developing a comprehensive understanding of intellectual property rights (IPR) takes considerable study and continual review of the legal literature. However, certain terminology and concepts that are regularly applied in this area are easily learned and assimilated. This basic knowledge is vital to effectively identify and manage intellectual property (IP). This chapter presents basic facts and concepts to assist the scientist, the administrator, the government official and the non-IP attorney to recognize and appropriately handle several different forms of IP.

Without basic knowledge of the laws that protect owners of IP and the procedures that must be followed to secure protection of these valuable discoveries, one could very easily give away the fruits of one's intellectual efforts. For example, when F.H. Erbisch was a researcher at a small university, he was unaware that his research had resulted in an invention. Approximately 8 years thereafter, another university announced that its researcher had been issued a patent on the very same invention! The patented invention has been very successful. It has earned the university and its researcher millions of dollars and saved many lives. Had the author's university educated its researchers and administrative staff on the basics of IP law, the invention may not have been 'lost' to the author. Since that time, the author has become a recognized expert in the field of technology transfer and, in his administrative roles, has endeavoured to educate researchers and administrators worldwide to properly manage their creations.

While the recognition and appropriate handling of IP are important,

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it is also necessary to know when to pursue the services of an IP professional who is fully trained in IP law and is registered to practise within the particular jurisdiction in which protection is sought. Although it is possible to obtain protection for certain IP without professional assistance, this is not recommended given the constant flux of procedural and legal requirements to secure such protection. These highly trained individuals can assist inventors and institutions to develop an appropriate plan that ensures that their valuable scientific discoveries and artistic works are fully protected. Then, through licensing and other forms of technology commercialization, these fully protected ideas and creations can begin to provide recognition and rewards to the originating organization and its inventor.

In this chapter, the concept of IP is addressed first. Following this is a basic discussion of the various means of protecting one's IP rights in the USA. Although the procedures for obtaining protection of IP in other countries may differ from those in the USA, the basic premise for each of these means of protection is quite similar.

What are Intellectual Properties?

In contrast with real property (land) and other forms of tangible personal property, which has physical characteristics, IP (ideas, thoughts or products of one's intellectual efforts) is intangible. As long as these ideas or thoughts remain in one's mind and are not disclosed to others by expression in a tangible form, they remain the protected property of their creator and cannot be used by others.

With any type of property there exists the concept of property rights, or the ability for one to protect one's personal property from interference by others. Unlike tangible property, common access to certain forms of IP theoretically does not diminish its value. Accordingly, the traditional justification for protection of tangible property does not apply to IP. None the less, when IP is expressed in a tangible form, it can be legally protected if it is new.

IPR are created to prevent others from using one's invention or artistic work without one's express permission. The utilitarian or economic justification for protection of IPR in the USA appears in the Constitution, which grants Congress the authority to legislate in order 'to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries'.[1] However, the origins of IP protection can be traced back to the 4th century BC, where in Aristotle's *Politics*,

[1] US Const. Art. I, § 8, cl. 8.

Hipodamus of Miletos calls for a system of rewards for those who discover things useful to the state.[2] Later, the chief minister under Elizabeth I used the grant of patents as a mercantilist instrument to entice foreign artisans to introduce continental technologies into England in what would today be called a 'strategic international trade' policy.[3] This same policy later became the basis of the current US and international patent system.

IPR are private rights that are ordinarily protected under one of four legal theories: patent, copyright, trademark and trade secret. They were created to ensure protection against unfair trade practice. Owners of IP are granted protection under state, federal and/or international law, under varying conditions and periods of time. This protection includes the right to: (i) defend their rights to the property they created; (ii) prevent others from taking advantage of their ingenuity; (iii) encourage their continuing innovativeness and creativity; and (iv) assure the world a flow of useful, informative and intellectual works.

With the growing recognition of IPR, the importance of worldwide fora on IP is realized. Many small and multinational corporations and universities, as well as entire industries, now recognize the benefit of protecting their rights in IP internationally. Accordingly, countries have signed numerous agreements and treaties and have developed organizations to oversee their application. Some of these agreements and treaties include the General Agreement on Tariffs and Trade (GATT), the World Intellectual Property Organization (WIPO) and the Trade-related Aspects of Intellectual Property Rights (TRIPS) treaty.

The desire to promote effective protection of IPR in the international trade forum has grown immensely. All of the previously mentioned agreements have been created to promote a balanced international trading field and to prevent the international trade of counterfeit goods. Another important reason to justify these agreements and their enforcement is the protection of IPR in underdeveloped countries and to enable these countries to create a sound and viable technology base. In doing so, developing countries are better prepared for participation in international trade.

Most stable and economically developed countries have IP laws that govern the issuance and enforcement of patents, trademarks and copyrights. Careful review of these laws should be undertaken to ensure protection within each respective jurisdiction. In the USA, protection of IP is available under patent, trademark/trade dress, copyright and/or trade secret. Each creation should be evaluated in the light of each of these methods to ensure that comprehensive IP protection is obtained.

[2] See R.P. Merges *et al.*, Intellectual Property in the New Technology Age 121 (1997).
[3] See R.P. Merges *et al.*, Intellectual Property in the New Technology Age 122–123 (citing Mandich, *Venetian Patents (1450–1550)*, 30 J. Pat & Trademark Off. Society 166, 177 (1948)).

What is a Copyright?

Copyright is often thought of as a special territory for artists, authors and composers. This is because not all forms of IP are entitled to protection under copyright. Specifically, copyright protection subsists in 'original works of authorship fixed in any tangible medium of expression'.[4] Pursuant to this definition, there are three requirements for obtaining protection.

First, the subject matter one desires to protect via copyright must be 'original'. It cannot be a mechanical reproduction of pre-existing material, a form, nor may it be a mere title, short phrase, name or slogan. Secondly, the IP must be a 'work of authorship'. Examples include literary works; musical works and any accompanying words (lyrics); dramatic works including any accompanying music; pantomimes and choreographic works; pictorial, graphic and sculptural works; motion pictures and other audiovisual works; sound recordings; and architectural works. Copyright protection is also available for compilations and derivative works. However, such protection extends only to the material contributed by the author and does not imply any exclusive right in the pre-existing material. Thirdly, the work of authorship must be 'fixed in a tangible medium of expression'. For example, the work must be written down, typed or drawn on paper, or stored on some medium (now known or later developed) in which the work can be perceived, reproduced or otherwise communicated, either directly or with the aid of a machine or device.

Once established that a particular work of authorship is entitled to copyright protection, the owner has the exclusive rights to reproduce the work, prepare derivative works based upon the work and distribute copies or phonorecords of the work to the public by sale or other transfer of ownership, or by rental, lease or lending. In the case of literary, musical, dramatic and choreographic works, pantomimes and pictorial, graphic or sculptural works, including the individual images of a motion picture or other audiovisual work, the owner has the exclusive right to perform or display the copyrighted work publicly.

Copyright prevents the unauthorized copying of a work of authorship. It does not extend to any idea, procedure, process, system, method of operation, concept, principle or discovery, regardless of the form in which it is described, explained, illustrated or embodied within such work. Consequently, while the written protocols to a particular scientific process cannot be photocopied and distributed if they contain substantive text or diagrams that constitute a 'work of authorship', copyright law does not prevent one from carrying out the process described in the writing and using or selling the resultant product. This is the territory of patents.

One particular limitation on the exclusive rights granted to an owner

[4] 17 USC §102(a).

of a copyright is the 'fair use' of the work, including such use by reproduction in copies or phonorecords for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship or research. Other limitations on the rights exclusive to the owner of a copyright include, *inter alia*, reproductions made by libraries and archives, the sale or dispossession of a particular copy or phonorecord by the owner of such copy without the authority of the copyright holder (the 'first sale doctrine'), the performance or display of a work by certain institutions for limited or non-commercial purposes, the secondary transmission of broadcast signals for particular purposes, certain ephemeral recordings and reproductions of computer programs, as well as reproductions for the blind or other individuals with disabilities, which are all performed without infringement of copyright.

Upon its creation, an original work of authorship is automatically protected under copyright so long as it is original and fixed in a tangible medium of expression. Initially, the author or authors of the work hold ownership to the copyright. Accordingly, the authors of a joint work are coowners of copyright in the work. Copyright in a work created by an employee within the scope of his or her employment (a 'work made for hire') is generally held by the employer. The rights provided under copyright are personal property rights and can be transferred in whole or in part. However, ownership of a copyright is distinct from ownership of any material object in which the work is embodied. Therefore, transfer of ownership of a material object, including the copy or phonorecord in which the work was first formed, does not convey property rights in any copyright.

The term of protection provided by copyright depends upon when it was first created. A work created in the USA on or after 1 January 1978 has a copyright that will endure for a term consisting of the life of the author and 70 years after the author's death. In the case of joint authorships, the 70 year period will begin at the death of the last surviving author. The copyright of anonymous works, pseudonymous works and works made for hire endures for a term of 95 years from the year of its first publication, or a term of 120 years from the year of its creation, whichever expires first. Copyright of a work, if registered prior to 1 January 1978 and subsisting on that date, will endure for 28 years from the date it was originally secured and will be entitled to a 67 year extension.

Registration of a copyright claim in the US Copyright Office is not a condition of copyright protection. As stated above, copyright protection for original works of authorship is automatic once fixed in a tangible medium of expression. However, the law affords certain advantages to those who adhere to certain formalities. First, a notice of copyright should be placed on publicly distributed copies and should consist of the following three elements: (i) the symbol © (the letter C in a circle), the word 'Copyright', or the abbreviation 'Copr.'; (ii) the year of first publication of the work; and (iii) the name of the owner of copyright in the

work. The notice should be affixed to the copies in a manner and location as to give reasonable notice of the claim of copyright.

To register a claim of copyright, the owner of copyright in a work published in the USA must deliver to the Copyright Office two complete copies of the work (one copy in the case of an unpublished work), together with a completed application for copyright registration and the obligatory fee. If all is in order, the Register of Copyrights will register the claim and issue to the applicant a certificate of registration bearing the seal of the US Copyright Office. The certificate contains the information given in the application as well as the number and effective date of the registration.

Although not a condition of copyright protection, no action for infringement of the copyright in any US work can be initiated until registration of the copyright claim has been issued. Infringement includes any violation of the exclusive rights of the copyright owner as noted herein, including the importation of unauthorized copies of works into the USA. Remedies for copyright infringement include injunctions, impounding and disposition of infringing articles, the copyright owner's actual damages and any additional profits of the infringer that are attributable to the infringement and are not taken into account in computing the actual damages. Statutory damages in cases of wilful infringement may also be awarded, as well as costs and attorneys' fees. In cases where a person wilfully infringes a copyright for commercial advantage or private financial gain, criminal penalties can be imposed.

The agriculture industry regularly utilizes copyright as a means of protecting certain IP. Written product descriptions and label directions containing substantive text or diagrams for the use of a particular product are just two examples of subject matter that can be protected by copyright. Although many countries recognize the copyrights of other countries, it is best to secure a copyright in the jurisdiction in which protection is desired.

What is a Trademark?

'Trademarks' are any letters, words, phrases, logos, shapes, symbols, colours, sounds or other similar devices used in commerce by a producer or manufacturer to identify and indicate the source of its goods. The trademark assists the consumer in distinguishing the goods of one producer from those manufactured or sold by others. For example, when a consumer opens a cheeseburger wrapper imprinted with two golden arches, he or she immediately knows that the cheeseburger inside is a McDonald's cheeseburger and not that of one of its competitors.

'Service marks' use similar devices to identify and distinguish the services of one entity from those of others. In contrast, 'trade names' identify the entity itself rather than the goods or services it provides. Finally, 'trade dress' signifies a product's shape, colour, packaging and

overall appearance, which may serve as a designator of the origin or manufacturer of a product.

Traditionally, the function of trademarks has been 'to identify the origin or ownership of the goods to which it is affixed'.[5] However, some insist that the primary purpose of a trademark is to protect a company's investment in research and development, marketing and the reputation a company has spent years creating in the eye of the consumer from theft by a competitor. Companies spend millions of dollars annually to create an image that differentiates their products from their competitors and is instantly recognized in today's market. This recognition alone is worth millions of dollars and is used in advertising of the product. Another benefit of the trademark is its use in maintaining quality control in products. Consumers rely on trademarks to help identify merchandise and services of consistent quality. A company must maintain a consistent level of quality in their trademarked products in order to remain competitive and protect the image it has expended so much to create.

Rights in a trademark are established through use of the mark in connection with goods and services in commerce. However, these rights are limited to the geographical area in which the trademark user does business. If the mark is used in commerce that Congress is empowered to regulate, i.e. interstate commerce or commerce with a foreign country, the trademark user may register the mark with the US PTO. Federal registration gives rise to the presumption that the registrant is entitled to exclusive use of the mark throughout the USA, and cuts off the ability of junior users in geographically remote trading areas to extablish rights of any confusingly similar mark.

Federal registration of a trademark is initiated through submission of either a 'use' or 'intent-to-use' application, depending upon whether the mark has yet been used in the ordinary course of trade. The application is then categorized as being within one or more particular international classifications of goods or services, and reviewed by an examining attorney at the US PTO to determine whether it meets the requirements for registration. It is often recommended that the registrant have a professional trademark availability search and opinion prepared by a trademark attorney prior to filing an application for federal registration. Although such a search is not required, the results obtained can prove useful when considering whether to file the application. The US PTO receives more than 300,000 trademark applications annually, a number that continues to grow. On average, an application will be pending for between 1 and 2 years prior to the grant of the trademark.

A proper trademark grammar should be used in order to notify the public of the user's claim to trademark rights. The designation TM (trademark) or SM (service mark) should be prominently displayed in

[5] Hanover Star Milling Co. v. Metcalf, 240 US 403, 412 (1916).

conjunction with the mark on the product itself or any associated advertising literature. It is not necessary to have the mark registered, or even have an application on file, in order to use either of these designations. However, only after the mark is registered at the US PTO may the owner use the designation ® (federally registered). The use of the ® symbol may enhance the measure of damages recoverable in an action for trademark infringement.

Trademark law, unlike patent and copyright, confers a perpetual right. As long as the trademark continues to identify a single source, anyone using a similar mark, which creates a 'likelihood-of-confusion' as to the origin of the goods or services, or creates a perception that the defendant is somehow associated with the registrant, may be liable for trademark infringement. A federal trademark registration has an initial term of 10 years, with available 10-year renewal terms. However, the perpetual right granted by trademark depends on its use. After the 5th year of the initial trademark registration, the owner must submit a declaration to the US PTO, signifying that the trademark is being used commercially, or the registration will be cancelled and the trademark rights will cease to exist. A similar document must be filed upon renewal.

Given the commercial value provided by trademarks, multinational companies spend fortunes to maintain their respective trademark rights around the world. Although trademark law differs from country to country, there are agreements in place that provide some measure of assurance that a company's trademark in one country does not go unprotected in another. For example, the North American Free Trade Agreement (NAFTA) preserves registration of marks under the trademark law of the issuing country, but ensures that each member country (Canada, Mexico and the USA) provides uniformity in its trade law. This avoids circumstances wherein 'pirates' register a large US company's trademarks in a particular country, wait until the company markets the product in that country and then charges the company excessive amounts of money for the use of its own trademark. In our consumer-oriented market, the commercial value of trademarks continues to rise, and with new global markets opening daily, the value of effective trademarks is sure to exceed all expectations.

What is a Patent?

A patent is the exclusive right granted to a patent holder to prevent all others from practising an invention for a limited period. What particular right the patent holder has depends on which country issued the patent. In the USA, in order for an invention to be protected, the inventor must file an application for patent in the PTO within 1 year of having it publicly disclosed. Once issued, the patent provides the patent holder with

the legal right to create a monopoly by excluding others from making, using, selling, offering for sale, or importing into the USA, its territories or possessions, what is covered by one or more claims of the patent. This right to exclude others from the invention is limited to a period of 20 years from the date that the application for patent was first filed.

The US Patent Act provides that 'whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor'.[6] The justification for the issuance of patents is to promote the progress of science and the useful arts. Patent law promotes such progress by giving the inventor the right of exclusion, which can be used to profit from the invention. However, in exchange for this right, the inventor must disclose all enabling details describing the invention, so that when the 20-year patent right expires, the public may have the opportunity to develop and profit from the use of the invention. Specifically, the inventor must disclose the 'best mode' contemplated by the inventor of carrying out the invention, at the time of filing the application.

There are three types of patents: (i) plant patents; (ii) design patents; and (iii) utility patents or 'regular patents'. Plant patents are granted for newly discovered asexually propagated plant varieties, other than tuber-propagated plants or plants found in an uncultivated state. Like a utility patent, a plant patent provides 20 years of protection. However, in comparison with utility patents, few plant patents are applied for in any given year.

In contrast to a utility patent, which protects functional characteristics, the design patent protects ornamental characteristics. Moreover, the lifespan of a design patent is only 14 years. This patent type prevents any individual or organization from copying a unique design and profiting from their actions. Examples of companies that commonly apply for design patents include toy, souvenir, industrial and automotive manufacturers. As noted above, the utility patent constitutes the largest percentage of all issued patents. It is most commonly used by companies, universities and individual inventors to protect the results of their research and development efforts.

In order for the US PTO to issue a utility patent, the inventor must establish that the invention is novel (new), non-obvious to one skilled in the particular field of the invention and has utility (usefulness). First, the novelty requirement refers to the prior existence of the invention. If the invention described in a pending application is identical to an already publicly disclosed invention, the novelty requirement will not be met. When this occurs, the invention is said to be 'anticipated' and, thus, unpatentable. Next, the requirement for utility refers to the practical use

[6] 35 USC §100.

of the invention. If the invention provides a product or process that fulfils a particular need, then the invention fulfils this requirement for patentability. Finally, the non-obviousness requirement refers to the degree of difficulty required to invent or discover the subject technology. If the invention is so obvious that anyone having ordinary skill in the particular field would have discovered it, then it most likely does not meet the requirement of being non-obvious. The main point to consider when assessing whether the invention is non-obvious is the situation at the time of the discovery. What might appear obvious in hindsight at the time of the patent application examination may not have been so obvious at the time of discovery. If the invention satisfies all three requirements, plus several procedural requirements in accordance with Patent Office rules and procedure, the application for utility patent will be allowed to issue as a patent.

Improvements to an existing invention can also be protected by way of a utility patent. Although some improvements are not considered to be sufficiently novel in view of a parent invention, other improvements are so innovative and useful that they become inventions in and of themselves. Improvements that are just too obvious or are so limited that they do not warrant the costs associated with securing a patent can be considered 'know-how' of the original invention. Most biotechnology inventions are filed as utility patent applications as opposed to plant patents. This is because as a utility patent it is possible to protect the modified genetic sequence, rather than the plant as a whole, and to control the use of the genetic material of a number of plants and for multiple uses such as pharmaceutical, pest protection, herbicide resistance, oil production, etc.

In the USA, an inventor has up to 1 year after an initial public disclosure, use, sale or offer for sale of an invention in which to file a patent application. However, the ability to file patent applications in foreign countries is lost if the US application is not filed before public disclosure of the invention. Also, the USA follows a 'first-to-invent' patent system, wherein the person who first invents a patentable process or apparatus is granted a patent even though a rival inventor, who invented the same thing at a later time, files for a patent first. Elsewhere in the world, the person who files their patent application first, regardless of when the invention was first developed, obtains the patent. This type of system is called 'first-to-file'.

A patent is only enforceable in the country that issues it. While a Patent Cooperation Treaty (PCT) application can provide additional time in which to decide in what particular nations an applicant wishes to obtain patent protection, a separate 'national stage' application for each individual country must be prepared and filed at the end of the PCT term. The cost for filing in a number of countries is great and costs can easily exceed US$100,000. If one does not pursue or obtain protection in a

country, anyone within that particular country may use, manufacture and sell the invention. However, products produced in non-patent countries cannot be imported or sold in countries where patent protection has been secured.

While a copyright is granted upon creation, a patent application may take more than 2 years to prosecute through the US Patent Office. The term of an issued patent can be reduced or extended in response to delays caused during its prosecution. While a utility patent for a mechanical device may be granted within 18 months, biotechnology patents may take 30 months to issue. Applications for US plant and utility patents are published by the US PTO 18 months after they are filed, unless the applicant expressly requests non-publication and certifies that the invention disclosed in the application has not and will not be the subject of an application filed in another country or under a multinational international agreement that requires publication of applications at 18 months after filing. A patentee whose application was published may collect reasonable royalties from any party who practised the invention between the date of publication of the application and the date the patent issues.

The preparation of a patent application is quite complex and generally an attorney is required to draft and prosecute the application. Particularly important is the drafting of patent claims. Claims are the portion of the patent that describes the essential elements of the invention and provide the basis for legal enforcement of the patent. No one may practise what is covered by the claims without the patent holder's permission. The selection of an attorney is important, as an attorney familiar with the field of the invention can more efficiently draft broader claims than one who is unfamiliar with the particular field. Given the attorney time associated with the drafting and prosecuting of patent applications, patents cost far more than copyrights or trademarks. For biotechnology patents, costs are seldom less than US$10,000, and generally much more. A copy of an issued US patent is provided in Appendix 1.1 at the end of this chapter.

Copyright, trademark and patent are the basic means of protecting creations and discoveries. There are two additional means of protection, each of which has advantages over the basic methods described above. These means of protection include trade secret and plant variety protection and are discussed in further detail below.

What is a Trade Secret?

Protection of certain confidential and economically viable information via trade secret provides an interesting alternative to the other forms of

IP rights protection discussed herein. According to the US Uniform Trade Secrets Act, a trade secret is any information that derives independent economic value from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use. The information sought to be protected under trade secret must be the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Consequently, a trade secret can be any information that gives a company a competitive advantage over its competitors and which the company takes reasonable precautions to maintain as secret.

Trade secret protection has no definite term. It may last as long as the company can keep the context of the trade secret from becoming public knowledge. Accordingly, a company's confidential information can remain perpetually protected, so long as it remains secret. For example, the Coca Cola Company has kept the formula of its base syrup flavouring a secret for over 100 years. In addition, the Polaroid Company has kept its instant film chemical formula out of public knowledge by closely guarding this tangible but restricted knowledge.

Trade secrets are not protectable from independent discovery or invention, such as reverse engineering. Thus, once the public or a competitor is aware of how to make a product or ascertains the nature and identity of the trade secret, protection is not enforceable. Disclosure can occur by: (i) publication by the owner, his/her employee, or someone else; (ii) selling a commercial product that embodies the secret; or (iii) inadvertent disclosure by accident or mistake.

In order to support a claim for misappropriation of trade secrets, the owner must show that reasonable precautions were taken to maintain secrecy. Trade secret rights are commonly kept and enforced through confidentiality, invention and non-competition agreements between companies and their employees, licensees and customers. Other methods include limiting disclosures to only certain individuals, marking of proprietary items as 'confidential', maintaining physical security of facilities and designing products that do not openly disclose the secret or that can be obtained via reverse engineering.

Ordinarily in the case of new employees, the employer company will require the new employee to sign an agreement that grants the employer trade secret protection. Trade secrets protected under agreements are often non-patented technologies involving significant time and costs expended by the company and, in certain cases, rejected or failed company projects. Although the company's aim in having their employees execute these agreements is to prevent competitors from enticing away key personnel, in reality, the employee's mobility and betterment are deemed pre-eminent to the competitive business interests of the employers. Departing employees are often reminded of their obligations under contract during an exit interview and severe penalties can be imposed on those who expressly breach agreements protecting a company's trade secrets.

Trade secret law provides remedies to companies for misappropriation of confidential information by competitors or employees either by theft or other improper means, or use in violation of executed confidentiality and other similar employment contracts. These remedies can include monetary damages such as the company's lost profits, reasonable royalties for use of the trade secret or profits made by the defendant as a result of the misappropriation. When irreparable injury is shown, an injunction can be imposed to prevent the defendant from using or disclosing the misappropriated secret. In addition, certain criminal penalties can be applied.

Trade secrets are much more common in private industry, where scholarly publication is not required and the value of information is dependant upon how well it can be kept secret from competitors and the public. In contrast, universities and government laboratories are encouraged and sometimes required to share their findings through publication and presentation, making it almost impossible to maintain a trade secret.

Trade secrets are sometimes the only asset that allows a company to operate in today's highly competitive markets. Companies spend millions of dollars on security measures to protect their valuable trade secrets. In many instances, trade secret is the foundation of a free enterprise and marketable product.

There is no direct cost for obtaining protection for trade secrets. However, the costs of maintaining a trade secret can be great. Costs include developing and entering into employment agreements, policing of employees and such agreements, and taking reasonable steps to prevent other companies from learning about the secret.

What is Plant Variety Protection?

Plant variety protection (PVP) enables discoverers of new varieties of plants that are sexually reproduced or tuber propagated to secure IP rights protection for that new variety for a term of 20 years (25 years for trees, shrubs and vines). Given that plant patents only cover asexually reproduced plant varieties, PVP picks up where the scope of security provided under a plant patent falls short. In addition, several advantages to this type of protection over plant and utility patents exist: (i) the cost is much lower (US$3025[7] compared with US$10,000–20,000); (ii) the application is simplified (a breeder can complete the required form and an attorney is not needed); (iii) the requirements for protection are less strenuous than those for patenting; and (iv) the IPR provided are quite similar to plant patents.

PVP, as with other types of protection, is only enforceable in the country for which protection has been granted. In the USA, a Certificate

[7] While subject to change, this amount includes US$2705 for the application and examination, plus the certificate fee of US$320 upon issuance of the certificate.

of Protection is awarded to the owner of a variety after examination demonstrates that it is new, distinct from other varieties, genetically uniform and stable through successive generations. The owner of a variety under PVP has the exclusive right to multiply and market the seed of that variety – a personal property right that can be assigned or licensed to another. However, two exemptions exist. Under the Research Exemption, a breeder can use protected seeds to develop a new variety. In addition, the Farmer's/Home Gardener's Exemption allows the collection and saving of seed for the sole use of replanting on the farmer's or gardener's land. These exemptions are unique from plant and utility patents, whereunder the mere use of collected seed would infringe the owner's rights.

Generally, PVP is not sought for transformed or transgenic plants (i.e. plants into which genes have been incorporated through biotechnology), but for plants or varieties that have been developed through traditional breeding. Protection of transgenic plants or varieties is more appropriate under a utility patent. Sexually reproduced plants or varieties of crop plants are usually economically viable for 5–10 years, depending upon the rate of disease and pest infestation. Breeders are continually developing new varieties and a breeder may have one or more new varieties ready for release each year. The high cost of and length of time required for patenting would prohibit most breeders and companies from obtaining protection for these varieties. Consequently, PVP provides an appropriate and alternative means for safeguarding their IP rights. (See Chapter 5 for a more in-depth review of plant variety protection.)

Traditional Knowledge

Traditional or indigenous knowledge, an area of original work, has little or no national protection, as do other types of IP such as literary creations (copyright) or inventions (patent). Presently any one can copy traditional knowledge information and use it in any manner without obtaining permission from the originators or 'owners' of this knowledge. Anyone using this knowledge for financial/economic gain is under no obligation to share this gain with the originators or 'owners' of this knowledge. Presently the WIPO is working to remedy this situation and developing recommendations for the use of this knowledge and means for sharing financial/economic gain.

Traditional knowledge is that information/knowledge that has been developed by indigenous people in various regions of the world. This knowledge has been transmitted orally across generations of groups or communities of indigenous people. Therefore, this knowledge often has a cultural context, a collective ownership and is constantly evolving. The

following are all part of traditional knowledge: medicinal materials, rituals and practices; agricultural practices; ecological considerations; music; dance; poetry; stories; artistic endeavours; and spiritual expressions.

Two major problems confront the area of traditional knowledge: (i) exploitation of the knowledge for economic benefit for others along with little or no concern for those who 'owned' the knowledge; and (ii) rejection of the traditions by new generations along with the encroachment of modern life styles, which dilutes the knowledge and may lead to its loss.

Protection of traditional knowledge has a number of important facets. It can preserve certain rights of the 'owners'. It can provide a knowledge base for the 'owners'' community and for humankind. It can create practical benefits and cultural enrichment opportunities for many people. It can increase socio-economic opportunities and developments globally. It can provide opportunities for benefit sharing. It can provide a long-term and secure enriched life for many, especially the 'owners' and originators of the knowledge. The world looks to WIPO to provide the needed protection for traditional knowledge and for its preservation for the enrichment of all mankind.

Summary

IP, when expressed in a tangible form, can be protected from unauthorized use. Literary works, including computer software or source code, are protected by copyright; symbols and brief key phrases that identify the source of a product or service are protected by trademark; and inventions are protected by patent. The costs and time required to obtain protection under these methods vary, with copyright being the least expensive (free) and quickest (immediate upon creation), and patent being the most expensive (several thousands of US dollars) as well as the most time consuming (up to and sometimes more than 3 years).

Two other types of protection are available. One is trade secret, where as long as the IP is kept 'secret', it is protected. The other is plant variety protection, which provides an adequate and inexpensive means of protecting certain sexually reproduced plants. Although protection under copyright and trade secret can be said to transcend national law, other methods of IP protection are only enforceable in the country for which one has applied for and obtained protection. Violation of any of these means of protection is subject to injunction and various types of punishment including fines and imprisonment.

Appendix 1.1.

The US patent shown here is owned by Michigan State University. The numeric indicators within the patent mark the various sections and illustrate the information provided in the patent document. The legend to these numeric indicators is provided below.

Cover page

(1) Patent number in bar code; (2) patent number; (3) date of issue of patent; (4) last name of first named inventor; (5) title of patent; (6) inventor's full name and city of residence; (7) owner or assignee of patent; (8) serial number assigned to patent application; (9) date on which application for patent was filed; (10) relevant patents and publications noted by applicant against which patent application was compared by patent examiner to check novelty and non-obviousness of invention; (11) name of primary and assistant patent examiners at US PTO; (12) name of university's patent attorney who undertook filing and prosecution of the application; (13) summary or abstract of the invention; (14) number of claims and drawing sheets.

Drawing sheet

This sheet gives a schematic illustration of some of the various components of the invention. A brief description of what is illustrated in the figures is provided in the text of the patent. The drawings include reference numbers that set out the structural components of the invention.

Text

This patent has five sections: (1) background information on the invention; (2) a more complete summary of the invention (as compared with the abstract); (3) a brief description of what is presented in the drawing sheets; (4) a detailed description of the invention with reference to the figures; and (5) a numbered claims section, setting out the boundaries of the invention presented in the patent. Note that each column of the patent text is numbered rather than each page.

2

Acquiring Protection for Improved Germplasm and Inbred Lines

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Introduction

This chapter explores the intellectual property (IP) issues involved in traditional breeding and in moving from natural material to the improved lines that are marketed themselves or used as parents of a hybrid. The chapter begins with a review of access to unimproved germplasm and the implications of international agreements affecting such access. It then considers relevant forms of IP protection as applied in the USA. These include the plant variety protection (PVP) system, the regular patent system and trade secrecy. The chapter concludes with a description of enforcement.

The Interrelationships Between Intellectual Property and Biodiversity

Ultimately, much of the agricultural germplasm of the world comes from the developing nations. It was, for example, Mexico in which maize was domesticated and the Andes in which the tomato and the potato were domesticated. It is the developing nations, too, that contain wild relatives or land races, sometimes incorporating resistances and other characteristics that may be of interest to a contemporary plant breeder. At one time, the scientific norm was to collect germplasm freely in any nation, including developing nations, and to use it in breeding. As the world's gene banks were organized during the 1970s, the collections were made on a similar basis – the return to the source nations would be through the

 Intellectual Property Rights in Agricultural Biotechnology. Second Edition (eds F.H. Erbisch and K.M. Maredia)

benefits of the improved varieties developed with the assistance of the collected material. However, during the 1970s, the developed nations moved quite strongly to adopt PVP, a form of intellectual property protection on plants to be discussed below. There arose concerns, based on the perception that it was unfair for the source material contributed by the developing nations to be transferred freely, while breeding activities contributed by developed nations were being rewarded with intellectual property rights.

These concerns led to political movements within the Food and Agriculture Organization (FAO), which created a Commission on Plant Genetic Resources and passed an International Undertaking on Plant Genetic Resources in 1983 (FAO, 1983). They also became major factors shaping the United Nations Convention on Biological Diversity, signed at Rio de Janeiro in 1992. There have been continuing negotiations within the FAO Commission, looking towards recognition of a right of the small farmer who has contributed to the genetic resource through the selection of seeds over the generations and creation of a fund for compensating source nations for transfers of genetic materials. These led to a tentative agreement in July 2001 (FAO, 2001), which was approved at the FAO Conference in November 2001. This agreement envisions a system under which those who commercialize crops, developed using genetic materials deriving from the international public sector, will pay into a fund to be used for programmes for 'farmers in developing countries, especially in least developed countries, and in countries with economies in transition, who conserve and sustainably utilize plant genetic resources for food and agriculture'. This is to be implemented through material transfer agreements (MTAs), i.e. agreements between the suppliers and recipients of the public genetic materials, in which the recipients commit themselves to make the necessary payments. There are to be no payments for transfers of material for research or commercialization of material that is available for further research and breeding. Although approved in 2001, the treaty has not been ratified and therefore is not in force. Because of this lack of ratification, negotiation sessions to settle a number of important issues have not been held. The text of the International Treaty on Plant Genetic Resources is available online (www.fao.org/ag/cgrfa/itpgr.htm).

The Convention on Biological Diversity itself includes carefully negotiated provisions governing genetic resources, as part of a much broader package oriented towards conservation of biological diversity in its natural habitats and in collections. The Convention's Article 19 affirms the sovereign rights of nations over their genetic materials, but leaves it clear that those genetic materials that were earlier transferred out of their nation of origin have entered the public domain and can be used freely for any purpose (Barton, 1992).

The clear implication of the Biodiversity Convention is that, in general, no further genetic material will be collected from any developing nation except pursuant to an MTA, agreed between the collector and appropriate national authorities, that will govern the arrangements under which the material is transferred. These may include an allocation of profits or a provision that the material cannot be used commercially without a further agreement allocating profits. There may also be provisions that, for example, restrict the acquisition of intellectual property rights (IPR) on the material, and there will normally be a prohibition of transfer of the material without building a chain of responsibility. Not all nations have yet adopted the legislation needed to enforce this right that they hold under the Convention. Moreover, some nations, looking to the costs of preparing and implementing these agreements and looking to the benefits of free exchange of genetic material, may choose not to require restrictive MTAs. This Biodiversity Convention system will further be supplemented by arrangements under the 2001 Treaty. Thus, it will be necessary for a breeder to consider these legislative and contractual arrangements in order to ensure good title to the material used in a breeding programme.

Plant Variety Protection

There are two significantly different regimes for the protection of plant breeding materials: the PVP (plant variety protection or plant breeders' rights) system and the regular patent system. For general reviews of the application of these systems to plant agriculture, see Baenziger *et al.* (1993), Hamilton (1993a), Parr (1993), Roberts (1996) and Strachan (Chapter 5, this volume).

The regime designed specifically for traditional plant breeding is the PVP system. It is designed to give these breeders an increased incentive to develop new varieties while respecting their traditions of exchanging material. The US version passed in 1970 and since updated (7 USC §§2321–2582) grants protection to varieties that are 'new,' 'distinct', 'uniform' and 'stable' (7 USC §2402). To be new, the variety must not have been sold previously, although there is a grace period of 1 year, and longer for foreign use. Distinctness requires that the variety be clearly distinguishable from previous varieties – this is not as severe an inventive step requirement as is typical of patent law. Uniformity requires that any variations be 'describable, predictable, and commercially acceptable'. Stability requires that, when reproduced, the variety 'remain unchanged with regard to [its] essential and distinctive characteristics … with a reasonably degree of reliability'. Moreover, seeds of the variety must be deposited (7 USC §2422).

The PVP law applies to sexually reproduced plants and tubers. There was an earlier law, the Plant Patent Act of 1930 (35 USC §§161–164), that applies to varieties that propagate asexually and is applied by the Patent Office, which can consult with the Department of Agriculture (27 CFR §1.167).

Protection under PVP is by means of a certificate granted by an office of the Department of Agriculture upon receipt of a relatively simple and inexpensive application. The variety must be given a name (7 USC §2422), and this name becomes an important part of the marketing of the variety and may be given trademark protection as well.

Protection is for 20 years, or 25 years in the case of a tree or vine (7 USC §2483). The certificate entitles its holder to be the exclusive marketer of the relevant variety and also of the product of the variety. This right may be licensed to others. The certificate does not, however, prevent others from using the variety in efforts to breed further varieties, nor does it prevent farmers from re-using harvested material (7 USC §2541). Farmers had at one time also been able to sell their seed under some circumstances (Asgrow Seed Co. v. Winterboer, 513 US 179 [1994]); this right was significantly narrowed in the 1994 revision of the act (PL no. 103–349, 6 October 1994).

The PVP laws of various nations are harmonized through an international treaty, e.g. UPOV (1978, 1991) (named after the French language acronym for the International Union for the Protection of New Varieties of Plant). This treaty establishes standards for PVP legislation and requires its parties to offer one another's breeders the opportunity to obtain PVP certificates as if they were nationals. Under the older versions of this treaty (e.g. UPOV, 1978), nations were required both to allow use of protected materials for breeding of additional new varieties and to allow farmers to re-use their harvest for seed purposes. Article 15 of the new (1991) version, which came into force in April 1998, permits nations to allow farmers to re-use seed, but does not require them to do so. As noted above, the USA has made this authorization. Article 14 of this new version adopts a concept of 'essentially derived variety', a concept implemented at 7 USC §2541. A breeder remains free to use a protected variety and to make any change in such a variety, but is subject to the rights of the owner of the initial variety if that change is so small as to leave the new variety 'essentially derived'. Examples listed in this article are varieties made 'by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering'.

There is strong evidence that adoption of a PVP system in the USA increased private sector plant breeding (Butler and Marion, 1985), and the rise of biotechnology-based breeding offers no reason to question this judgement. It is also clear, however, that PVP does not provide adequate

protection for a firm that has sequenced an important gene and transformed plants with it. If PVP were the breeder's only protection, another breeder could purchase the protected material and breed the gene into a new variety. This is in no way an infringement of PVP rights, but it clearly significantly decreases the market potential for the initial breeder.

The Regular Patent System

For the reasons outlined above and many others, biotechnology-oriented breeders have turned to the regular patent system. After initial hesitation, surmounted by Diamond v. Chakrabarty (447 US 303 [1980]), the US Patent and Trademark Office began to issue many different types of regular patents protecting biotechnological methods of breeding and biotechnologically produced plants.

Patent system concepts

As will be recalled from Chapter 1, an invention or discovery must be novel, non-obvious, useful and enabled in order to be patentable. 'Novelty' means that the invention has not been anticipated by publication or use in the market (35 USC §102). (Unlike most nations, the USA allows a 1 year grace period between the time of a publication and the time at which a patent can be filed.) 'Non-obviousness' means that the invention is an actual advance in the state of the art. The US definition is that a patent shall be denied if 'the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains' (35 USC §103). Likewise, the standard of 'utility' (35 USC §101) is intended as one way to distinguish basic scientific advances from patentable inventions. 'Enablement' means that the patent describes a way to carry out the invention, typically through a description in the patent (35 USC §112). Sometimes enablement may also require deposit of actual genetic material, e.g. a seed, when this line cannot be reliably produced on the basis of a written description. This seed must be available to the public once the patent enters into force (37 CFR §1.808). Such a deposit can be made at any of a number of institutions and there is an international treaty allowing each nation to recognize deposits in other nations (Budapest Treaty, 1977). Under some circumstances, enablement may require presentation of the gene or amino acid sequences; this sequence must be provided in machine-readable form (37 CFR §§1.821ff).

The patent itself includes both a description of how to practise the invention and a statement of claims, which precisely define the exclusive rights conferred by the patent. In evaluating the possibility of infringe-

ment, it is these claims that must be consulted. Obtaining a patent is both slower and more expensive (typically US$20,000 for legal costs and filing fees) than obtaining a PVP certificate; expenses of global coverage can easily rise into hundreds of thousands of US dollars. The term of protection is 20 years from the date of application, with the possibility of extension in the event of certain delays (35 USC §154).

Varieties of patents

The Board of Patent Appeals and Interferences of the US Patent and Trademark Office has interpreted Diamond v. Chakrabarty to mean that any plant can be patented, provided that it satisfies the basic standards for intellectual property. In particular, it has concluded that the availability of a special PVP system for plants does not exclude patentability of plants under the regular patent laws (Ex parte Hibberd, 227 USPQ 443 (1985)) (US Patent and Trademark Office, 1985). It would be very difficult to read Chakrabarty in any other way. Although there had been some debate about the desirability of such 'double protection', it has thus become generally assumed in the USA that one can obtain both a patent and a PVP certificate for the same organism. In the USA, it is possible to obtain a patent on a gene and its application in a plant and on basic processes and inventions in the way discussed in the previous chapter of this book. We will note these possibilities very briefly, and then turn to the protections available on a plant or inbred line itself. The patent on a gene and on transformed plants utilizing the gene is frequently written with a number of claims covering, for example: an isolated or purified protein, the isolated or purified nucleic acid sequence that codes for the protein, plasmids and transformation vectors containing the gene sequence, plants (or seeds for such plants) transformed with such vectors and containing the gene sequence, and the progeny (or seeds) of such plants. For an example that shows a number of these claims, see Zaitlin *et al*. (1997). This structure of the claims, which reach isolated versions of the gene or protein, protects the patent holder against use of the gene by another biotechnologist, but leaves anyone free to use and breed organisms containing the gene naturally. Another category of patents covers basic processes and inventions. Here, there are many extremely important patents, e.g. on transformation processes, promoters, the use of virus coat proteins to confer resistance, and antisense technology.

It is also possible in the USA to obtain claims covering broad groups of transgenic plants, as exemplified by the Agracetus patents on all transgenic cotton (Umbeck, 1992). The breadth of such a patent is extremely significant and has been the subject of severe criticism (Stone, 1995). The underlying legal issue is enablement; the claims are supposed to reach as far as the disclosure enables a person of ordinary skill in the art to do the claimed action

without 'undue' experimentation. When a person applies for a patent after transforming several strains of a species with several different genes, there is an obvious question as to whether that person has actually enabled transformation of all strains with all genes. Although it is likely that no one knows the answer to this question at the time of patent application, the burden of proof in the USA on this issue is on the patent office to show that a claim was not enabled. Comparable issues are posed by claims based on plant descriptions, for example, 'a hybrid maize plant characterized by a genetic factor which confers an extra leaf phenotype, said genetic factor being capable of transmission to progeny substantially as a single dominant gene' (Muirhead and Shaver, 1985). As with the cotton patent, there is the question of whether the disclosure of one or several lines with the particular characteristics should give rights over all such lines.

Finally, there are the patents of most importance to this chapter, those on a specific variety. It has become normal practice for US breeders to seek regular patent protection for a variety as an alternative or supplement to PVP and trade secrecy (for inbred lines used as parental hybrids). If this technique is successful, it can be used to protect against a farmer's seed re-use and against breeders seeking to use the material. This use of the regular patent system may thus provide a way to avoid the limitations of the PVP system.

The claims in a variety patent will specify a variety by its name or by a designation, for example:

> 1. Seed of maize inbred line designated PHDG1 and having ATCC (American Type Culture Collection) Accession No. 97663.
> 2. A maize plant and its parts produced by the seed of claim 1 and its plant parts.
>
> (Piper, 1997)

The claims may cover inbred lines or hybrids; they may cover seeds or plants; and they may attempt to extend to progeny. The patent just cited goes on:

> 10. A method for producing first generation (F_1) hybrid maize seed comprising crossing a first inbred parent maize plant with a second inbred parent maize plant and harvesting the resultant first generation (F_1) hybrid maize seed, wherein said first or second parent maize plant is the maize plant of claim 2.
> 13. An F_1 hybrid seed and plant produced by the method of claim 10.

Another approach to claiming progeny is 'a hybrid corn plant, wherein at least one ancestor of said hybrid corn plant is the corn plant [of the claimed inbred line]' (Strissel *et al.*, 1992). For general discussion of such claims and other examples, see Seay (1993).

The validity of these patents was resolved by the US Supreme Court, in J.E.M. Ag Supply v. Pioneer Hi-bred Int'l Inc., 534 US 124 (2001). This case held such patents valid in spite of the argument that Congressional

enactment of the special PVP regime for varieties, giving the breeder a weaker package of rights, should be interpreted as excluding the more general patent regime for the same form of invention.

The Supreme Court's decision does not resolve all issues here and several should be noted. First, the evaluation of obviousness in such patents is quite difficult. In Ex parte C, 27 USPQ.2d 1492 (Board of Patent Appeals and Interferences, 1992), the Board appeared to assume that breeding of a new soybean variety could provide the basis for a regular patent, but did not accept the mere fact of difference from previous varieties as adequate:

> We have reviewed the data and the declaration but are unpersuaded of patentability because there is nothing of record which explains why the differences between the claimed variety and a rot resistant variety such as 'Pella 86' are so significant and unexpected that they should weigh more heavily than the numerous similarities between the claimed variety and the varieties of the cited prior art.
>
> 27 USPQ.2d at 1497

More recently, however, the Federal Circuit (a higher review group) held in In re Sigco Research, 36 USPQ.2d 1380 (Federal Circuit, 1995), that it was not obvious to apply conventional plant breeding techniques to obtain true-breeding sunflower plants whose oil had an oleic acid level of 'approximately 80% or greater'.

In order for regular patents to work for the breeder interested in preventing farmers from re-using the seed, it is essential that, with an appropriate claim, it will be possible to control use of the progeny of the plant. This judgement requires an interpretation of two doctrines. One is the doctrine of patent exhaustion – in general, once a patented product is sold, the purchaser is free to use it in any way and has, in effect, an implied licence for using the product, reselling it, etc. The other doctrine is that replication of an invention is an infringement. The issue may be effectively resolved by the Pioneer Hi-bred case. However, for any patented organism, the expectation among US intellectual property experts is that the exhaustion doctrine will be interpreted in such a way as to uphold a patentee's rights against a purchaser's use of the seed deriving from a patented variety. It has already been recently narrowed to uphold a patent holder's restriction of use of a medical device to a single use (Mallinckrodt Inc. v. Medipart Inc., 24 USPQ.2d 1173 (Federal Circuit, 1992)).

For a breeder, another important issue is whether such claims can be effective in preventing a third party from using the inbred line as a parent or crossing a variety with an inserted gene into a different variety and marketing that variety. In other words, will they be effective in overriding the PVP principle that another breeder is free to use protected material? The answer to this question is significantly less defi-

nite. Clearly, there is no control against using the material for breeding purposes unless the claims cover that use. Thus, a claim for a specific seed or a plant would seem not to prohibit crossing of the seed or the plant with another line – the new seed and plant are not within the claims of the patent. On the other hand, if the claims of the patent include use of the material as the parent of anything else, there is at least a prima facie argument that breeding is prohibited. One counter-argument is that, as will be noted in connection with restrictive licence clauses, there is a strong policy that a purchaser of material in commerce has the right to study and 'reverse engineer' it in order to ensure that scientists and technologists are able to build on and improve one another's work. A counter-argument less likely to be effective is that the use is within the 'experimental use' exemption to patent infringement. This is a court-made exemption designed in the first instance to permit academic use of an invention. Although its exact scope is unclear, except in one specific context where there has been legislation (35 USC §271(e)(1) permitting experimental work with patented pharmaceuticals in preparation for entering the market at the time the patent expires), it is generally interpreted as applying only to academic research and not to commercial research (Eisenberg, 1989; Bruzzone, 1993). The Court of Appeals for the Federal Circuit, the key appellate court for patent law, has twice interpreted this exemption as being very narrow (Embrex v. Service Engineering Co., 216 F.3d 1343 (Federal Circuit, 2000); Madey v. Duke University, 307 F.3d 1351 (Federal Circuit, 2002)). The Supreme Court has chosen not to review the latter decision.

Trade Secrecy

One of the most important forms of intellectual property protection is the trade secret system, a combination of legal principles of contract law and of legal principles against misappropriation of another's information. The contractual component recognizes and encourages private enforcement of contracts designed to protect information, e.g. confidentiality agreements between a firm and its employees. The misappropriation components protect the holder of a trade secret against, for example, one who comes into the laboratory and secretly copies laboratory notebooks. To benefit from trade secret protection, a bit of information (which can include genetic material) must 'derive independent economic value' from 'not being generally known' and 'be the subject of efforts that are reasonable under the circumstances to maintain its secrecy' (Uniform Trade Secret Act §1[4]). The effective term of the protection is as long as the secret is valuable and secret, rather than being limited to a fixed term as with the patent and PVP systems.

This body of law provides a technique for control of inbred lines used as parents of a hybrid. These lines need not be released publicly in order for the hybrid to be marketed. They can be protected through a combination of physical protection of the materials themselves and of contracts with employees and those involved in producing seed. This does not, however, prevent a third party from attempting to reconstruct the parental lines from the marketed hybrid.

Firms are therefore attempting to supplement PVP and patent protection by using contractual provisions to prohibit 'reverse engineering' of the material they sell to farmers. When one buys the seeds, the label or the reverse of the sale bill contains a restrictive provision, whose key relevant language is, for example:

> Purchaser hereby acknowledges and agrees that the production from the … [s]eeds herein sold will be used only for feed or processing and will not be used or sold for seed, breeding, or any variety improvement purpose.
>
> (Stine, quoted in Hamilton, 1993b)

The legal effectiveness of this approach is subject to debate. First, there is a question of whether this mechanism of achieving contract agreement is effective, and there are cases on both sides of the issue in such contexts as warranty disclaimers on herbicides. Moreover, as noted above, there has been a tradition in US law that one has a right to 'reverse engineer' products that are commercially marketed, reflecting a sense that maintaining this right permits more rapid scientific advance. Hence, it is possible that, even if they would otherwise be enforceable under contract law principles, these agreements are unenforceable because they are 'preempted' (effectively overridden) by federal standards on intellectual property protection (or, in other legal systems, by a competition law provision). The leading recent Supreme Court example is Bonito Boats, Inc. v. Thunder Craft Boats, Inc. (489 US 141 [1989]), which struck down a state statute prohibiting the use of direct moulding processes to copy boat hulls, on the theory that the state statute 'conflicts with "strong federal policy favoring free competition in ideas which do not merit patent protection" '. (The quotation is from an earlier case dealing with patent licences (Lear, Inc. v. Adkins; 395 US 653 [1969]).) There was also an early Plant Patent Act decision that regarded as an antitrust violation a contract between a breeder and its distributors that contained a number of restrictive provisions including one under which the original breeder sought to retain title to all sports deriving from the supplied material (Yoder Bros Inc. v. California–Florida Plant Corp., 537 F.2d 1347 (1976)). Nevertheless, in 1996, a federal judge in the US Midwestern area upheld a somewhat parallel agreement governing use of a CD-ROM containing an uncopyrightable database (ProCD, Inc. v. Zeidenberg, 86 F.3d 1447 [7th Cir. 1996]). Much of the new case's logic could be applied by analogy to the seed labels, but will not necessarily be followed in other regions of the nation.

Enforcement

Enforcement of all of these rights is by private suit before a court (except for certain uses of intellectual property rights to prevent imports of a protected product or of the product of a protected process, in which case the suit may be before the International Trade Commission under 19 USC §1337). The process is dependent on the initiative of the holder of the right, who generally has the burden of proof to demonstrate infringement, which, in the case of a patent, means showing that the allegedly infringing variety is within the scope of the claims of the patent. Although there is a presumption that the patent is valid, the defendant may attempt to show that the patent is invalid, for example by showing that there was previous publication, that the invention was obvious, or that the patent disclosure was not enabling or did not reflect the patentee's best mode of performing the invention at the time of filing (35 USC §112). If the plaintiff succeeds, it can frequently obtain an injunction against use of the product (35 USC §283), in addition to damages, which are based on its actual market loss or on an estimate of a reasonable royalty (35 USC §284). In the case of trade secrecy, damages can also include a requirement that the defendant disgorge any profits gained from use of the secret.

The process can be very expensive, reaching in the USA about US$500,000 per side per claim litigated. This is a result of the legal fees and the expenses spent in each side's effort to obtain information from the other. Expenses are especially high in the USA, because that nation still has a 'first-to-invent' system, implying that two firms, each seeking to demonstrate that it was the first to invent, will have to present evidence about the detailed history of the research process. Moreover, there may be extensive research through obscure journals in an effort to show that the invention was not novel. There may also be substantial expert testimony about the precise interpretation of the claims, and there may be a need to develop significant scientific evidence in order to demonstrate the similarity of two varieties.

The realities of contemporary litigation in this area are exemplified in Pioneer Hi-Bred International v. Holden Foundation Seeds, 35 F.3d 1226 (8th Cir. 1994). This was a trade secrecy suit, in which Pioneer claimed that Holden had used one of its inbred maize lines in the development of competing lines. The case was tried before a judge and the judge admitted evidence from isozyme electrophoresis, reverse phase high performance liquid chromatography and growout tests. These demonstrated substantial similarity between the Pioneer and the Holden lines. Holden was then unable to provide evidence persuading the court that it had developed the line independently in a way that did not infringe Pioneer's rights. It lost a judgement for over US$46 million.

Such litigation is rare because it is so expensive, and there have been very few suits over specific lines. Among the important exceptions is a case holding that a patent under the Plant Patent Act can be infringed only by an asexually propagated product of the protected variety (Imazio Nursery, Inc. v. Dania Greenhouses, 69 FR2d. 1560 [CAFC, 1996]). At this time, firms appear to be using their litigation budget primarily for disputes over fundamental biotechnology patents, e.g. rights in various aspects of the use of *Bacillus thuringiensis* as in Plant Genetic Systems v. Mycogen Plant Science, Inc. 933 F. Suppl. 514 and 519 (MDNC, 1996) and Mycogen Plant Science, Inc. v. Monsanto Co., 1995 US Dist. LEXIS 20383 (SDCa, 1995), rather than for disputes over specific lines, and they have, of course, been seeking to avoid litigation by building portfolios of patents to be used defensively or for cross-licensing. It may therefore be some time before we have solid judicial answers to the uncertain issues discussed above.

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3

Transferring Intellectual Properties*

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Introduction

The use of protected intellectual properties (IPs) is prohibited unless the owners allow others to use them. While, the owners can 'tie up' the IPs for the term of protection, most protected IP has value to the innovator and/or to others. In general, the innovator or discoverer of an IP/innovation or its owner will want to transfer the IP/innovation to gain either fame or financial rewards. If the value is primarily to the innovator/discoverer, it is often kept by the innovator/discoverer or freely shared with others. More commonly, the innovator/discoverer will attempt to commercialize the IP and, in essence, the innovator/discoverer can trade the IP for money through the sale or licensing of the IP. Licensing is the most common method of transferring technology.

In this chapter the various methods of transferring technologies will be covered and, in particular, licensing of an innovation will be emphasized. For clarity the word 'innovation' will be used instead of IP and 'innovator' will be used in place of innovator/discoverer throughout this chapter. However, this does not mean that the information only applies to inventions – it will apply to any type of IP/innovation. The examples will be based on experiences in the USA.

Free, Public Distribution of the Intellectual Property

Free, public distribution of an innovation is one method of disseminating it. It rarely occurs in the biotechnology arena because innovators want to

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recoup costs associated with the innovation and to make money. Most innovators believe that their innovations are valuable, even when it appears that they have little value. However, occasionally the innovator will give away an innovation in exchange for another innovation. The innovator may also receive good will or recognition.

For example, an innovator develops a process (P_1) for creating substance S. P_1 is more time consuming and more costly than other processes (P_2, P_3, P_4) used to create substance S, but is elegant in its methodology. Also assume the innovation is patentable. Yet instead of patenting, the innovator decides to disclose the innovation at the annual meeting of innovators because no one will ever use the innovation commercially. By giving away the otherwise valueless innovation, the innovator earns good will and praise from colleagues for the elegant method of producing substance S.

Besides good will, giving an innovation away can be an excellent way to market it. One industry that relies on this method is the computer software industry. Some software companies give away a smaller, scaled-down version of their product to entice users into purchasing a licence for a fully functional product. Other software innovators program the software to stop functioning after a certain date. In both cases, the innovator retains control because he/she can program the software. This prevents the user from using the product in a manner contradictory to the owner's wishes. Free public distribution is used basically as a marketing tool to advertise the product in hopes of securing a commercial licence. Unlike software, once the biotechnology information is given to the user or potential licensee, there is usually no way to restrict its use.

Sale of Intellectual Property

Selling an innovation is one method of commercializing it. Sale of an innovation is called an assignment. Assignment of a patent occurs in one of three ways. The owner of the patent conveys: (i) the whole patent, comprising the exclusive right to make, use or sell the patented innovation throughout the USA; (ii) an undivided part or share of that exclusive right; or (iii) the exclusive right under the patent throughout a specified geographical location.

There are three primary problems associated with the sale of an innovation. The first is the determination of the sale price. At what price should the innovator sell the IP? This is a difficult question. The innovator's sale of an innovation happens only once. Therefore, the innovator must recoup, in the sale price, all monetary value in one transaction. Since most biotechnology innovations are not fully developed at the sale date, it is extremely difficult to put a monetary value on the innovation. If the price is too high, no one will purchase the innovation. If the price is

too low, the innovator loses money when the innovation becomes commercially valuable.

The second problem associated with the sale of an innovation is that the seller loses his/her right to use the innovation without permission from the new owner. Once the innovator sells the patent, *all* of his/her interest in that innovation is sold. Since, by definition, patent rights are the right to prevent all others from making, using or selling the innovation, even the innovator will be prohibited from using the innovation – even in his/her own research!

The third problem associated with the sale of an innovation is the loss of control over the innovation. Like the sale of any article, once a sale is made, the sale is final and the seller's control of the innovation is lost. Additionally, once sold, the buyer may use the innovation in ways never intended by the innovator. The buyer may even use the innovation in an unscrupulous manner.

In summary, because of these three problems, the sale of an innovation is quite rare. The inability to determine a fair price and the loss of control make licensing a better option.

Licensing the Intellectual Property

To solve the sale price, future use and control problems associated with assignment or sale of an innovation, the innovation can be licensed. The document accomplishing this is the licence agreement (sometimes called simply a licence). A licence is generally a written document that describes the rights and obligations of the parties in a precise manner. Put a different way, a licence is a binding, revocable privilege to use the innovation, for a fixed number of years, in a fixed territory in exchange for money or other compensation. It is a contractual relationship and, in the USA, its enforcement is governed by contract law. Licences are usually between two persons but could be among three or more persons. 'Person' means an individual such as an independent researcher, a university or even a company.

Because licences are usually negotiated contracts, the parties to a licence can put into the licence agreement virtually anything they desire. (See the licence at the end of this chapter as an example.) These provisions or conditions in a licence are called the licensing terms. There are a few basic elements of a licence that are dictated by contract law. By enumerating exactly what the parties intended, the licence not only guides the parties as to what they can and cannot do in the future, it also provides a dispute mechanism to which the parties can refer when misunderstandings or disagreements occur. That is, the properly crafted licence prevents disagreements, but if a misunderstanding occurs, it helps fashion a workable remedy.

It is important to note that the innovator or company who licenses out an innovation is called the licensor. The person who receives the benefit of the innovation in a licence is called the licensee.

Licensable innovations include: patents, trademarks, copyrights, trade secrets or other recognized forms of innovation. Licensing has two distinct advantages over sale of the innovation. The first is that the innovator retains ownership of the innovation. Traditionally, ownership of any property carries with it certain rights. In the case of patents, this includes the right to forbid others from using, making or selling the innovation. Trademarks, copyrights and the other forms of innovation have their own rights associated with ownership. By retaining ownership, the innovator is assured of being able to protect those rights by legal action if necessary.

One form of legal action against a person who is using the innovator's innovation without permission is an infringement lawsuit. Patent owners or inventors would file a patent infringement lawsuit, copyright owners or authors would file a copyright infringement lawsuit and trademark owners would file a trademark infringement lawsuit. It should also be noted that the person who unlawfully uses the innovation is called an infringer.

The innovator who successfully sues an infringer can get two possible things: money (called damages) and/or a court order telling the infringer to stop making, using or selling the innovation (this is called an injunction). Furthermore, damages awarded in an infringement lawsuit vary significantly from nothing to millions or hundreds of millions of dollars!

One of the main benefits of a licence is the ability to retain control of the innovation. Let us look at a brief example. Suppose a researcher working at a university develops a particular crop variety specially designed to resist pests. The researcher would like to try some initial field tests on a larger scale and experiment with local farmers who are, in turn, interested in the researcher's pest-resistant crop. Since our innovator works at the university, the university is the innovation owner and wants to make sure the new crop does not cause harm to the environment. Because of crop management and the innovator's desire to control the experiment, the innovator and university would like to control where the crop is planted, how the crop is handled and whether or not a second generation of crops could be planted from the mature crop (sometimes called breeders' rights). The university is not interested in receiving a lot of money for the innovation right now but would nevertheless like to retain control of the crop since the university is hoping that in 3–5 years from now, the innovator's continued research will produce a finished marketable seed that would be highly valued.

While the sale of the innovation may give the university some initial money, the university believes that the innovation will be most

valuable in 3–5 years. How would the university value the innovation now since the research is in its infancy? And once sold, the sale of the innovation would give the innovator and university virtually no control of how the crop is used. Yet a properly drafted licence agreement could contain terms addressing each of these issues. As stated earlier, what goes into a licence agreement is generally up to the parties. In this case, the university could negotiate licence terms that, because of environmental concerns, would require the crop to be planted in certain soils or stored in proper containers. The university could also negotiate that the seeds are only for a single season, that next season's crop must again be licensed from the university and that the farmers using the seeds are forbidden to license or sell the seeds to others. Not only would this ensure that the licensee (the farmer) received the latest crop every year incorporating all the researcher's improvements, but the university would retain control over how and where the crop is used and planted. Additionally, the university is protected financially since the licensee could not sell or license the seed to others. Would the university continue to fund the crop research if another company could buy the seeds from farmers and continually grow and sell the seed to others year after year?

In this example, the crop research was in its infancy and the researcher did not expect a finished product for at least 3–5 years. However, assume that the university is reluctant to continually fund the research and does not want to wait 3–5 years to see any financial reward. The university's solution would then be to negotiate an initial payment into each licence agreement.

An initial payment (sometimes called a 'front-end' payment because it must be paid at the beginning of the licensing period) in a licence is a one time payment made by the licensee to the licensor simply for agreeing to the licence. By making the initial payment quite small, licensees are more willing to agree to the payment. Additionally, it provides the university with some needed money before the innovation is finished and helps to determine who is actually interested in the innovation. Because licence negotiations take time, effort and money, the initial payment helps to determine whether the potential licensee is committed to being bound by the terms of the licence and also whether the licensee is genuinely interested in the innovation. Without the initial payment, there would be less incentive for the licensee to follow the terms of the licence since the licensee never actually gave up anything of value to acquire the licence.

Ownership also carries with it certain implied rights. One such implied right in the USA is the right to 'shelve' the patent. (Some countries require an owner to exercise or use their patent or otherwise risk losing it.) Shelving means, figuratively, placing the patent on a shelf and doing nothing with it.

For example, an innovator has a patent on P_1, the process for creating substance S. Process P_1 uses the raw material M to create substance S. The innovator also sells the raw material M and is making lots of money on its sale. Next, the innovator invents and patents P_2, another process for making substance S. But process P_2 does not require the use of raw material M. To continue the sale of raw material M, the innovator shelves the P_2 patent, and the innovator does not use P_2 or allow others to use P_2.

The innovator can contract out some rights and retain others. For example, the innovator can license out all rights to the innovation with the exception of retaining the right to use the innovation for non-commercial purposes. This retainer right by the innovator enables the innovator to continue his/her research and is very common in licensing agreements, especially if the innovation was made in a university or government-supported research laboratory.

An additional example of licensing a part of an innovation is the sub-licence. The licensee is given the right to have others practise or do those things (use, make and/or sell) that are available to the licensee. For example, the innovator who patented process P_1 licenses the patent on process P_1 but retains the right to use the innovation for non-commercial purposes. The licensee, who has been given the right to sub-license, licenses out (sub-licenses) the patent to companies in Asia, the UK and Canada with restrictions that each can only sell, make or use the innovation in their respective country.

Important Components of a Licensing Agreement

As stated previously, a licence agreement is a personal, revocable privilege that gives the licensee (the technology recipient) a right not to be sued by the licensor for using the innovation. The licence is primarily used for voluntarily exchange of an innovation for money or some other consideration.

Because disagreements about what the parties intended occur often and are usually settled in court, many components of a licence are dictated by contract law. The remaining elements of the licence are particular to the technology involved and what the parties desire. (For example, although granting permission to reproduce a particular plant variety would be applicable in certain circumstances, it would be a meaningless provision if the technology were a mechanical device.)

While keeping these substantive requirements in mind, when drafting a licence agreement it is important to remember to write clearly, i.e. ambiguity should be avoided. However, pinpointing every little detail and thinking through every possible contingency would not only take large amounts of time, but would produce a licence document so large that it would be impractical to use. The key is to balance the need for certainty with the need for a practical, workable document.

When deciding how much detail to put in the licence, first keep in mind the value of the technology involved. The licence for a product valued at US$1500 may have fewer pages and requirements than a 10 year licence valued at US$1,000,000. Other factors to consider are the parties' backgrounds, knowledge, industry practices or standards and the desire for flexibility when an unforeseen circumstance occurs.

Also, try to avoid adding 'filler' to the licence, i.e. avoid legal terms that add ambiguity and uncertainty. Make each sentence clear, understandable and succinct. It is difficult for others to ascertain what the parties intended if they must re-read the sentence six or seven times or consult an attorney every time the agreement is read.

Finally, label the parts of the licence. Break the licence down into sections or articles and title each accordingly. This allows one to refer to other sections of the licence with pinpoint accuracy. Although there is no one licence that will work in all situations, there are provisions that are common to most licences. As stated, most of these common requirements are dictated by contract law – that is, they apply to all technology licences, irrespective of whether the licence is for a biotechnology or a mechanical device. A number of these 'common' provisions are listed in Table 3.1. Each provision will be briefly described and the purpose of each reported. A basic licensing agreement is included at the end of this chapter and will be referenced as the provisions are described. Seldom is the basic licence agreement used as presented here; it is usually modified for the particular innovation being licensed and for the potential licensee.

Table 3.1. Basic components of a licence agreement.

1. The parties
2. Whereas clauses
3. Definitions
4. Grant of licence
5. Financial considerations
   - (i) Initial payments
   - (ii) Running royalties
   - (iii) Patent costs
6. Research support
7. Reporting requirements
8. Diligence
9. Termination
10. Liability/warranty
11. Use of names
12. Agreement governance
13. 'Boilerplate'

The following are brief reviews of some of the components of a licence agreement.

1. *The parties.* Usually the parties of the licence are named in the first paragraph of the licence agreement: the licensor – who is licensing – and the other party as the licensee – the one obtaining the right to use the innovation. Each party's full name and address should be included. If a party has more than one principal place of business, make a note of these other addresses in the licence. This prevents confusion between companies with the same name. When dealing with corporations in more than one country, always state the name of the country in the address. After the names of the parties, a short-hand, capitalized notation is given in parentheses. This name is used in the rest of the document so that the entire name need not be written each time.

2. *Whereas clauses.* This portion of the licence gives the basis for the agreement. These clauses list certain facts about the licensee, the technology and the licensor, which simply state the position of the two parties to make the licence arrangement possible.

3. *Definitions.* Definitions are critical in technical and scientific documents and especially in legal documents. Definitions are very important in the licence agreement because many terms have more than one meaning. Remember it is important not to have ambiguity in the licence and both parties must understand the terms of the agreement. In the attached agreement, definitions are found in ARTICLE I. Here definitions include Licensed Patent Rights, Products and Net Sales. Other definitions often added describe the 'field' of use for the innovations being licensed and the 'territory' in which the licensee can operate. Additional definitions may describe genes, plant types or varieties and other technology-specific terms used later in the licence.

4. *Grant of licence.* This is a very important part of the licence. Through this provision the licensee is granted the right to manufacture, sell or use the innovation (ARTICLE II – GRANT OF EXCLUSIVE LICENCE). The licensee may be granted an exclusive licence or a non-exclusive licence. The exclusive licence assures the licensee that the innovation will not be licensed to any other party. With a non-exclusive licence the licensee may have competitors because the licensor can license the technology to another party or parties. The exclusive licence can have variations too – the licence can be exclusive for a geographical region rather than worldwide, or for a particular product rather than for all products that could be produced using the technology. The term of this licence can be limited to the protection period (for the life of the patent) or extend beyond the protection to include new innovation improvements which would be added to the licence (ARTICLE IX – TERM).

If the licence is exclusive and the licensor wants to continue to do research using the innovation, it is necessary to add a statement to the

granting clause that the licensor reserves the right to continue to do non-commercial research and development (ARTICLE II – GRANT OF EXCLUSIVE LICENCE).

5. *Financial Considerations.* Usually the licensor does not grant the licence without some financial consideration. There are three basic areas for financial consideration: (i) initial payment; (ii) royalties; and (iii) patent costs. The initial payment is made at the time the licence is signed by both parties (ARTICLE III – LICENCE PAYMENTS. 3.1. Initial payment and royalty rate). The amount is agreed through negotiation. The amount of payment depends upon the type of technology, the stage of development, the innovation protection period and the licensing company. If the initial payment is low, then the royalty rate is generally higher than when the initial payment is large. Usually the royalty is based upon the sale of the product, the net selling price of the product (ARTICLE I – DEFINITIONS. 1.3. Net Sales). The royalty rate is a percentage of the net selling price (ARTICLE III – LICENCE PAYMENTS. 3.1. Initial payment and royalty rate). Rarely are royalties based on licensee profits because of the difficulty of determining profit. To encourage the licensee to use the innovation and not shelve it, a provision for an annual minimum royalty payment is included in the licence (ARTICLE III – LICENCE PAYMENTS. 3.3. Minimum royalty). Patent costs are very high, especially when foreign protection is also sought. The licence can provide that the licensee pays all these costs and, in the case of foreign patents, the licensee may be granted the responsibility of deciding whether foreign filing is to be done and in what countries to file (ARTICLE XI – PATENT FILINGS AND PROSECUTING). In some instances, the licensee negotiates the right to deduct a portion of the patent costs from royalties.

6. *Research Support.* In the case of university innovations, few are completely developed, and they need further research and development before they will be marketable. The licensee is given an opportunity to have the innovator continue research on the innovation. The actual research will be governed by a separate research agreement, but the fact that the licensee will support research can be noted in the licence agreement.

7. *Reporting Requirements.* In order to ascertain the commercialization of the technology and the basis for royalty payment, the licensee is required to submit required periodic reports. The royalty payment is due at the time the report is submitted (ARTICLE IV – REPORTS, BOOKS AND RECORDS). The provision on diligence (ARTICLE VI – DILIGENCE) also has reporting requirements, but these reports are required only for a limited time and contain information of steps taken towards commercialization – these reports are much different from the required royalty-type reports.

8. *Diligence.* This provision is included in the licence to assure the licensor that the licensee will move ahead commercially with the innovation.

Through this provision the licensor can require the licensee to meet certain milestones within a defined period of time. Failure to satisfactorily complete these milestones can serve as a means of terminating the licence. The reporting requirements of this provision also provide the licensor the satisfaction of knowing how the innovation is being developed for commercialization (ARTICLE VI – DILIGENCE).

9. *Termination.* This provision provides a means for the licensee to terminate its relationship with the licensor, as well as for the licensor to terminate the arrangement. For the licensor to terminate and recover the technology, the conditions must be such that commercialization of the licensed technology is in jeopardy or the diligence terms are not being met. Without this provision the licensee could shelve, in some manner, the licensed technology and the licensor's technology would never be commercialized (ARTICLE VIII – TERMINATION OR CONVERSION TO A NON-EXCLUSIVE LICENCE and ARTICLE VI – DILIGENCE).

10. *Liability/Warranty.* Once the licensee begins to make, sell and/or use the licensed innovation, the licensor does not want to be responsible or liable for the product, so this provision provides that the licensee is responsible (ARTICLE XIII – MISCELLANEOUS. 13.4. Indemnity). Generally, the innovation licensed needs further development by the licensee. Since the licensor has not taken the innovation to the level of commercialization, the licensor cannot warrant that the technology will be free of defects at this higher level of development (ARTICLE XIII – MISCELLANEOUS. 13.8. Disclaimer of Warranty). While the licensor has used a patent attorney to draft and prosecute protection for the innovation, and a patent has been issued or granted, the licensor still cannot be sure that some company will not sue for infringement. Therefore, to protect itself the licensor includes a provision that states that it does not guarantee that the 'patent will be free of claims of infringement' (ARTICLE XIII – MISCELLANEOUS. 13.3. No representations of warranties regarding patents of third parties).

11. *Use of Names.* One of the ways the licensor is able to control the licensee is by not allowing the licensee to use the licensor's name in advertising. This prevents the licensee from using the licensor's name to endorse a product or imply that the licensor warrants or guarantees the product (ARTICLE XIII – MISCELLANEOUS. 13.6. Advertising).

12. *Agreement Governance.* The licensor wants to have any legal actions taken care of near the licensor's facilities to minimize any legal costs. This provision of the agreement names the geographical area in which any legal action brought against the licensor by the licensee will be held. If a university licenses an innovation to a company outside the university's country, the provision will also state that the laws of the university's country govern (ARTICLE XIII – MISCELLANEOUS. 13.1. Law of Michigan governs).

13. *'Boilerplate'*. Certain provisions included in a licence agreement must be included because of contractual considerations. These provisions are rarely negotiated. Often these provisions are given the general name of 'boilerplate'. Both the licensee and the licensor know that these provisions will be in the agreement and accept this condition.

Summary

Protected innovations can provide the innovator with several options for taking the innovation to the public. One method would be to make the innovation freely available to anyone at no cost and under no obligations. Another way would be to sell the innovation, but the innovator loses all control of the innovation. The preferred way to transfer innovations is through a licence because the innovator or the innovation's owner retains control. The licence agreement contains a number of provisions that the licensee is required to follow, all of which are to the benefit, often financially, of the innovator, the licensor, the licensee and/or society.

Appendix 3.1. Sample Exclusive Licence Agreement

This Agreement is made and entered into by and between_____, with an office at _____ (hereinafter called Licensor) and _____, with an office at _____ (hereinafter called Company).

WHEREAS Licensor has the right to grant licences under the licensed patent rights (as hereinafter defined), and wishes to have the inventions covered by the licensed patent rights in the public interest; and

WHEREAS Company wishes to obtain a licence under the licensed patent rights upon the terms and conditions hereinafter set forth:

NOW, THEREFORE, in consideration of the premises and the faithful performance of the covenants herein contained the parties agree to the following:

ARTICLE I – DEFINITIONS

For the purpose of this Agreement, the following definitions shall apply:

1.1. 'Licensed Patent Rights' shall mean:

(a) Patent Application Serial No. _____ filed _____ by _____. Or New Plant Variety registered and protected through _____.

(b) Any and all improvements developed by Licensor, whether patentable or not, relating to the Licensed Patent Rights, which Licensor may now or may hereafter develop, own or control.

(c) Any or all patents, which may issue on patent rights and improvements thereof, developed by Licensor and any and all divisions, continuations, continuations-in-part, reissues and extensions of such patents.

1.2. 'Product(s)' shall mean any materials including plants and/or seeds, compositions, techniques, devices, methods or inventions relating to or based on the Licensed Patent Rights, developed on the date of this agreement or in the future.

1.3. 'Net Sales' shall mean gross sales of Product(s) FOB place of manufacture of Products, less sales and/or use taxes, third party commissions, discounts, custom duties and shipping.

1.4. 'Confidential Proprietary Information' shall mean with respect to any Party all scientific, business or financial information relating to such Party, its subsidiaries or affiliates or their respective businesses, except when such information:

(a) Becomes known to the other Party prior to receipt from such first Party;

(b) Becomes publicly known through sources other than such first Party;

(c) Is lawfully received by such other Party from a party other than the first Party; or

(d) Is approved for release by written authorization from such first Party.

1.5. 'Exclusive Licence' shall mean a licence, including the right to sub-license, whereby Company's rights are sole and entire and operate to exclude all others, including Licensor and its affiliates except as otherwise expressly provided herein.

1.6. 'Know-how' shall mean any and all technical data, information, materials, trade secrets, technology, formulas, processes and ideas, including any improvements thereto, in any form in which the foregoing may exist, now owned or co-owned by or exclusively, semi-exclusively or non-exclusively licensed to any party prior to the date of this Agreement or hereafter acquired by any party during the term of this agreement.

1.7. 'Intellectual Property Rights' shall mean any and all inventions, materials, know-how, trade secrets, technology, formulas, processes, ideas or other discoveries conceived or reduced to practices, whether patentable or not.

1.8. 'Royalty(ies)' shall mean revenues received in the form of cash and/or equity from holdings from Company as a result of licensing and using, selling, making, having made, sub-licensing or leasing of Licensed Patent Rights.

ARTICLE II – GRANT OF EXCLUSIVE LICENCE

2.1. Licensor hereby grants to Company the exclusive licence with the right to sub-license others, to make, have made, use, sell and lease the Products described in the Licensed Patent Rights.

2.2. Licensor retains the right to continue to use Licensed Patent Rights in any way for non-commercial purposes.

2.3. It is understood by the Company that the Licensed Patent Rights were developed under _____ Grant No. _____. The _____ government has a non-exclusive, royalty-free licence for governmental purposes. (This paragraph is optional. It only applies to government-sponsored research innovations.)

ARTICLE III – LICENCE PAYMENTS

3.1. Initial payment and royalty rate. For the licence herein granted:

(a) Company agrees to pay a sign-up fee of _____ (_____).

(b) Company shall pay an earned royalty of _____per cent (___%) of Company's Net Sales of Products and fifty per cent (50%) of the sub-licensing receipts.

(c) Company shall pay an annual royalty of _____ (_____) for each leased Product.

3.2. Sub-licences. The granting and terms of all sub-licences is entirely at Company's discretion provided that all sub-licences shall be subjected to the terms and conditions of this agreement.

3.3. Minimum royalty: Company will pay Licensor, when submitting their royalty report a minimum royalty of _____ (_____) annually.

3.4. When a sale is made: a sale of Licensed Patent Rights shall be regarded as being made upon payment for Products made using Licensed Patent Rights.

3.5. Payments: all sums payable by Company hereunder shall be paid to Licensor in the currency of the _____ or in US dollars.

3.6. Interest: in the event any royalties are not paid as specified herein, then a compound interest of eighteen per cent (18%) shall be due in addition to the royalties accrued for the period of default.

ARTICLE IV – REPORTS, BOOKS AND RECORDS

4.1. Reports. Within thirty (30) days after the end of the calendar quarter annual period during which this agreement shall be executed and delivered within thirty (30) days after the end of each following quarter annual period, Company shall make a written report to Licensor setting forth the Net Sales of Licensed Patent Rights sold, leased or used by Company and total sub-licensing receipts during the quarter annual period. If there are no Net Sales or sub-licensing receipts, a statement to that effect be made by Company to Licensor. At the time each report is made, Company shall pay to Licensor the royalties or other payments shown by such report to the payable hereunder.

4.2. Books and records. Company shall keep books and records in such reasonable detail as will permit the reports provided for in Paragraph 4.1. hereof to be determined. Company further agrees to permit such books and reports to be inspected and audited by a representative or representatives of Licensor to the extent necessary to verify the reports provided for in paragraph 4.1. hereof; provided, however, that such representative or representatives shall indicate to Licensor only whether the reports and royalty paid are correct, or if not, the reasons why not.

ARTICLE V – MARKING

Company agrees to mark or have marked all Products made, used or leased by it or its Sub-licensees under the Licensed Patent Rights, if and to the extent such markings shall be practical, with such patent markings as shall be desirable or required by applicable patent laws.

ARTICLE VI – DILIGENCE

6.1. Company shall use its best efforts to bring Licensed Patent Rights to market through a thorough, vigorous and diligent programme and to continue active, diligent marketing efforts throughout the life of this agreement.

6.2. Company shall deliver to Licensor on or before _____, a business plan for development of Licensed Patent Rights, which includes number and kind of personnel involved, time budgeted and planned for each phase of development and other items as appropriate for the development of the Licensed Patent Rights. Quarterly reports describing progress toward meeting the objectives of the business plan shall be provided.

6.3. Company shall permit an in-house inspection of Company facilities by Licensor on an annual basis beginning at _____ .

6.4. Company failure to perform in accordance with either paragraph 6.1, 6.2 or 6.3 of this ARTICLE VI shall be grounds for Licensor to terminate this agreement.

ARTICLE VII – IRREVOCABLE JUDGEMENT WITH RESPECT TO VALIDITY OF PATENTS

If a judgement or decree shall be entered in any proceeding in which the validity or infringement of any claim of any patent under which the Licence is granted hereunder shall be in issue, which judgement or decree shall become not further reviewable though the exhaustion of all permissible applications for rehearing or review by a superior tribunal, or through the expiration of the time permitted for such application (such a judgement or decree being hereinafter referred to as an irrevocable judgement), the construction placed on any such claim by such irrevocable judgement shall thereafter be followed not only as to such claim, but also as to all claims to which such instruction applies, with respect to acts occurring thereafter and if an irrevocable judgement shall hold any claim invalid, Company shall be relived thereafter from including in its reports hereunder that portion of the royalties due under **ARTICLE III** payable only because of such claim or any broader claim to which such irrevocable judgement shall be applicable, and from the performance of any other acts required by this agreement only because of any such claims.

ARTICLE VIII – TERMINATION OR CONVERSION TO A NON-EXCLUSIVE LICENCE

8.1. Termination by Company: Company may, at its option, terminate the licence granted by this Agreement, provided Company shall not be in default hereunder, by giving Licensor ninety (90) days notice to its intention to do so. If such notice shall be given, then upon the expiration of such ninety (90) days the termination shall become effective; but such termination shall not operate to relieve Company from its obligation to pay royalties or to satisfy any other obligations, accrued hereunder prior to the date of such termination.

8.2. Termination by Licensor: Licensor may, at its option, terminate the licence granted by this Agreement if Company is in default in the payment of any royalties required to be paid by Company to Licensor hereunder or if:

(a) Default in the making of any reports required hereunder and such default shall continue for a period of thirty (30) days after Licensor shall have given to Company a written notice of such default.

(b) Default in the performance of any other material obligation contained in this agreement on the part of Company to be performed and such default shall continue for a period of thirty (30) days after Licensor shall have given to Company written notice of such default.

(c) Adjudication that Company is bankrupt or insolvent.

(d) The filing by Company of a petition of bankruptcy, or a petition or answer-seeking reorganization, readjustment or rearrangement of its business or affairs under any law or governmental regulation relating to bankruptcy or insolvency.

(e) The appointment of a receiver of the business or for all or substantially all of the property of Company; or the making by Company of assignment or an attempted assignment for the benefit of its creditors; or the institution by Company of any proceedings for the liquidation or winding up of its business or affairs.

8.3. Effect of termination: Termination of this agreement shall not in any way operate to impair or destroy any of Company's or Licensor's right or remedies, either at law or in equity, or to relieve Company of any of its obligations to pay royalties or to comply with any other of the obligations hereunder, accrued prior to the effective date of termination.

8.4. Effect of delay: Failure or delay by Licensor to exercise its rights of termination hereunder by reason of any default by Company in carrying out any obligation imposed upon it by this agreement shall not operate to prejudice Licensor's right of termination for any other subsequent default by Company.

8.5. Option of Company to convert to non-exclusive licence: Company shall have the right to convert this Licence to a Non-exclusive Licence at the same royalty rate as for the Exclusive Company, without right to sub-license and minimum royalties under **ARTICLE III**, Paragraph 3.3 shall not be due thereafter.

8.6. Return of Licensed Patent Rights: Upon termination of this agreement, all of the Licensed Patent Rights shall be returned to Licensor. In the event of termination of the agreement by Company or said conversion of the agreement by Company, Company shall grant to Licensor a non-exclusive, royalty-free Licence, with right to sub-license, to manufacture, use and sell improvements including all know-how to Licensed Patent Rights made by Company during the period of this agreement prior to the termination or conversion, to the extent that such improvements are dominated by or derived from the Licensed Patent Rights.

ARTICLE IX – TERM

Unless previously terminated as hereinbefore provided, the term of this Agreement shall be from and after the date hereof until the expiration of the last to expire of the licensed issued patents or patents to issue under the Licensed Patent Rights under **ARTICLE I**. Company shall not be required to pay royalties due only by reason of its use, sale, licensing, lease or sub-licensing under issued patents licensed by this Agreement that have expired or been held to be invalid by an Irrevocable Judgement, where there are no other of such issued patents valid and unexpired covering the Company's use, sale, licensing, lease or sub-licensing; provided, however, that such non-payment of royalties shall not extend to royalty payments already made to Licensor more than six (6) months prior to Company's discovery of expiration or an Irrevocable Judgement.

ARTICLE X – PATENT LITIGATION

10.1. Initiation. In the event that Licensor advises Company in writing of a substantial infringement of the patents/copyrights included in the Licensed Patent Rights, Company may, but is not obligated to, bring suit or suits through attorneys of Company's selection with respect to such infringement. In the event Company fails to defend any declaratory judgement action brought against any patent or patents of the Licensed Patent Rights, Licensor on written notice to Company may terminate the Licence as to the particular patent or patents involved in such declaratory judgement action.

10.2. Expenses and proceeds of litigation. Where a suit or suits have been brought by Company, Company shall maintain the litigation at its own expense and shall keep any judgements and awards arising from these suits expecting that portion of the judgements attributable to royalties from the infringer shall be divided equally between Licensor and Company after deducting any and all expenses of such suits; provided, however, Licensor shall not be entitled to receive more under this provision than if the infringer had been licensed by Company.

10.3. Licensor's right to sue. If Company shall fail to commence suit on an infringement hereunder within one (1) year after the receipt of Licensor's written request to do so, Licensor in protection of its reversionary rights shall have the right to bring and prosecute such suits at its cost and expense through attorneys of its selection, in its own name, and all sums received or recovered by Licensor in or by reason of such suits shall be retained by Licensor; provided, however, no more than one lawsuit at a time shall commence in any such country.

ARTICLE XI – PATENT FILINGS AND PROSECUTING

11.1. Company shall pay future costs of the prosecution of the patent applications pending as set forth in **ARTICLE I**, Paragraph 1.2 that are reasonably necessary to obtain a patent. Furthermore, Company will pay for the costs of filing, prosecuting and maintaining foreign counterpart applications to such pending patent applications, such foreign applications to be filed within ten (10) months prior to the filing date of the corresponding patent application.

11.2. Licensor shall own improvements by the inventors. Company shall pay future costs of preparation, filing, prosecuting and maintenance of patents and applications on patentable improvements made by inventors; however, in the event that Company refuses to file patent applications on such patentable improvements in (country) and selected foreign countries when requested by Licensor, the rights to such patentable improvements for said countries shall be returned to Licensor.

11.3. Preparation and maintenance of patent applications and patents undertaken at Company's cost shall be performed by patent attorneys selected by Licensor; and due diligence and care shall be used in preparing, filing, prosecuting and maintaining such applications on patentable subject matter. Both parties shall review and approve any and all patent related documents.

11.4. Company shall have the right to, on thirty (30) days written notice to Licensor, discontinue payment of its share of the prosecution and/or maintenance costs of any of said patents and/or patent applications. Upon receipt of such written notice, Licensor shall have the right to continue such prosecution and/or maintenance on its own name at its own expense in which event the Licence shall be automatically terminated as to the subject matter claimed in said patents and/or applications.

11.5. Notwithstanding the aforegoing paragraph of this **ARTICLE XI**, Company's obligations under such paragraphs shall continue only so long as Company continues to have an Exclusive Licence under the Licensed Patent Rights and, in the event of conversion of the Licence to non-exclusive in accordance with **ARTICLE VIII**, paragraph 8.5, after the date of such conversion:

(a) The costs of such thereafter preparation, filing, prosecuting and maintaining of said Licensed patents and patent applications shall be the responsibility of Licensor, provided such payments are at the sole discretion of the Licensor; and
(b) Company shall have a non-exclusive Licence without right to sub-license under those of such patents and applications under which Company had an Exclusive Licence prior to the conversion.

ARTICLE XII – NOTICES, ASSIGNEES

12.1. Notices. Notices and payments required hereunder shall be deemed properly given if duly sent by first-class mail and addressed to the parties at the addresses set forth above. The parties hereto will keep each other advised of address changes.

12.2. Assignees. This Agreement shall be binding upon and shall inure to the benefit of the assigns of Licensor and the successors of the entire business of the Licensor, but neither this agreement nor any of the benefits thereof nor any rights thereunder shall, directly or indirectly, without the prior written consent of Licensor, be assigned, divided or shared by or with any other party or parties.

ARTICLE XIII – MISCELLANEOUS

13.1. This Agreement is executed and delivered in the country of _____ and shall be constructed in accordance with the laws of the Government of _____.

13.2. No other understanding. This Agreement sets forth the entire agreement and understanding between the parties as to the subject matter thereof and merges all prior discussions between them.

13.3. No representations or warranties regarding patents of third parties. No representation or warranty is made by Licensor that the Licensed Patent Rights manufactured, used, sold or leased under the Exclusive Licence granted herein is or will be free of claims of infringement of patent rights of any other person or persons. The Licensor warrants that it has title to the Licensed Patent Rights from the inventors.

13.4. Indemnity. Company shall indemnify, hold harmless and defend Licensor and its trustees, officers, employees and agents against any and all allegations and actions for death, illness, personal injury, property damage and improper business practices arising out of the use of the Licensed Patent Rights.

13.5. Insurance. During the term of this agreement, Company shall maintain the following insurance coverage:

(a) Commercial general liability with a limit of no less than one million US dollars (US$1,000,000.00, option) each occurrence.

(b) Professional liability of no less than one million US dollars (US$1,000,000.00, option) each occurrence.

(c) Workers' compensation consistent with statutory requirements. Certificates of insurance shall be provided to Licensor upon request and shall include the provision for 30-day notification to the certificate holder of any cancellation or material alteration in the coverage.

13.6. Advertising. Company agrees that Company may not use in any way the name of Licensor or any logotypes or symbols associated with Licensor or the names of any researchers without the express written permission of Licensor.

13.7. Confidentiality. The parties agree to maintain discussions and proprietary information revealed pursuant to this agreement in confidence, to disclose them only to persons within their respective organizations having a need to know and to furnish assurances to the other party that such persons understand this duty on confidentiality.

13.8. Disclaimer of Warranty. Licensed Patent Rights is experimental in nature and it is provided WITHOUT WARRANTY OR REPRESENTATIONS OF ANY SORT, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OF NON-INFRINGEMENT. Licensor makes no representations and provides no warranty that the use of the Licensed Patent Rights will not infringe any patent or proprietary rights of third parties.

In witness whereof, the parties hereto have caused this agreement to be executed by their duly authorized representatives.

The effective date of this agreement is _____, 20___.

LICENSOR _____	COMPANY_____
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____

4

Capacity Building in Intellectual Property Management in Agricultural Biotechnology

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Introduction

Capacity building is the strengthening and/or development of human resources and their institutional support structures. In agriculture, biotechnology is currently applied to improve agricultural productivity in order to feed growing populations in an environmentally friendly manner. Biotechnology encompasses many factors, not just research, and includes policy, networking and management. In order to properly utilize the new and emerging tools of biotechnology, nations must take an integrated approach and build capacity in all these areas. Developing capacity in policy areas includes fostering experience and expertise in intellectual property rights (IPR), biosafety, food safety and commercial linkages. This chapter focuses on capacity building in IPR management, an important policy element for the proper use, access and exchange of new and emerging biotechnologies.

Large investments in new biotechnologies have been made by the private sector in developed countries. While many of these promising new biotechnologies reside in industrial countries, they may offer new ways in which developing countries could enhance their agricultural productivity. These technologies are often proprietary in nature and must be managed in a different way from non-proprietary technologies.

In the past, technologies developed by the public sector were freely exchanged, particularly agriculture-related technologies such as crop varieties and germplasm.

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The recent changes in the General Agreement on Tariffs and Trade (GATT) now require members of the World Trade Organization (WTO) to respect each other's IPR. In the past, public sector research in most developing countries was predominantly supported by their governments, which mandated that public sector institutions freely serve society. Therefore, technologies generated by the public sector were freely exchanged for research and development purposes without entering into any kind of commercial agreements. With the advent of biotechnology, this trend is now changing.

Capacity Building in Intellectual Property Rights

As the global community increasingly attempts to privatize the agricultural sector and access new and emerging technologies, many national governmental policies are changing to address IPR issues. In order to build a sound IPR framework, nations must address the issue of capacity building at both the national and institutional levels. The following sections discuss capacity building at both national and institutional levels using the USAID-funded Agricultural Biotechnology Support Project (ABSP) (formerly known as the Agricultural Biotechnology for Sustainable Productivity Project) as a case study where appropriate.

The ABSP project started in September 1991 as a cooperative agreement between the United States Agency for International Development (USAID) and Michigan State University (MSU). The ABSP project is a consortium of public and private sector institutions in the USA and developing countries and represents an integrated approach to agricultural biotechnology research and development programmes. It established links between a developing country's public and private sectors and the USA's public and private sectors (Maredia and Dodds, 1994; Ives *et al.*, 1998). Since the early 1990s, the ABSP project has assisted Egypt, Kenya, India, Indonesia, Costa Rica, Morocco and South Africa in the use and management of biotechnologies. For example, one area on which the project was focusing was building capacity in IPR management and technology transfer (Ives *et al.*, 1999).

The integrated approach to IPR capacity building includes the following areas: (i) awareness creation; (ii) human resource development; (iii) institutional development; and (iv) information access. These areas are discussed in the following sections.

Awareness Creation

Proper awareness of biotechnology-related issues must be created nationally. Since the IPR issues are closely tied in with the use and man-

agement of biotechnology, nations must create proper awareness among the general public, policy makers, scientists and administrators. It is very important that several approaches are used to create this awareness and many international programmes are involved in this process. For example, the ABSP project assisted developing countries on IPR issues through seminars, internships, workshops, one-to-one consultations and information delivery. The project organized several international and national workshops on various aspects of IPR management, including an IPR workshop in Cairo, Egypt, in January 1994 (Bedford and Maredia, 1994). Over 150 scientists and senior administrators from various public and private institutions in Egypt attended this workshop. In March 1996, the project organized a Plant Variety Protection (PVP) Workshop in Morocco attended by over 250 participants (Ives, 1997). Also, in January 1999, the project held a regional IPR workshop focusing on the impact of IPR on international trade in agriculture in East Africa attended by over 70 participants (www.iia.msu.edu/absp/workshop2.html).

Since biotechnology is a new addition to agriculture, many developing countries are trying to develop appropriate national or institutional IPR policies that meet the requirements of regional and international treaties. Scientists working within public sector institutions in developing countries are not fully aware of the importance of IPR issues and issues involved in the access and exchange of proprietary technologies.

In the USA, associations such as the Association of University Technology Managers (AUTM), the Biotechnology Industry Organization (BIO), the American Seed Trade Association (ASTA), various federal agencies and university intellectual property (IP) offices play an important role in creating general awareness of biotechnology-related IPR issues. Appendix 4.1 lists selected organizations and institutions that provide IPR-related information and offer training and capacity-building opportunities.

Human Resource Development

Human resource development addressing national policy issues

Since many biotechnologies are proprietary in nature, appropriate national policies related to IPR must be in place to access these technologies. When the ABSP project was initiated in 1991, most of the collaborating countries did not have IPR policies in place relating to agricultural biotechnology. Therefore, the project initially assisted in the area of appropriate IPR policy formulation. This formulation may require development, changes, revisions and/or amendments in legislation. To make these changes or revisions, policy makers must receive information regarding national and international biotechnology-related IP management issues.

To meet these educational needs, the ABSP project, under the leadership of Professor John Barton, organized an internship programme in IPR at Stanford Law School in 1993 (Barton and Bedford, 1993). The internship's goal was to educate both the policy makers and scientists in various agricultural biotechnology-related IPR issues. Subsequently, the ABSP project organized other IPR workshops and provided one-to-one consultations to help build a country's national IPR capacity. For example, in March 1995, the ABSP project organized a PVP and Patents Workshop in Jakarta, Indonesia, and assisted in drafting a new PVP law for Indonesia. This PVP law has now been approved by the Indonesian parliament. In Egypt, ABSP-trained personnel facilitated the inclusion of plant and food products into existing IPR legislation. Therefore, the impact of ABSP human resources development activities has been tremendous.

In addition to scientists and policy makers, patent examiners need to be trained to examine biotechnology-related patent applications efficiently. IPR legislation in many nations now allows patenting of agricultural biotechnology products. However, the patent examiners who examine these applications for patentability do not have an adequate background and knowledge of biotechnology. The US Patent and Trademark Office (US PTO) in Washington, DC, conducts patent application and examination training. Utilizing this resource, ABSP trained two patent examiners and one scientist from Indonesia. In its capacity-building activities, the ABSP project has always stressed the importance of developing links between legal and scientific personnel.

At the national level, capacity building is very important. Without proper awareness and education, policy makers and senior administrators who are responsible for formulating new policies cannot develop an appropriate IPR framework. Without an appropriate framework, scientists will not be able to access foreign technologies. Without access to new technology, increased agricultural production, necessary to feed a growing population, will probably not occur. The appropriate national IPR framework also allows countries and local scientists to protect their own inventions and to protect their genetic and biological resources.

Human resource development addressing institutional policy issues

The previous section discussed the IPR policies and capacity-building issues at the national level. The real challenge is implementing and enforcing broad national IPR policies at the institutional level. In other words, national IPR policy issues must be institutionalized. Trained human resources must be available at the institutional level to help to design and implement the agricultural biotechnology-related IPR policies.

IPR capacity building at the institutional level can have multiple benefits. Some benefits include assisting in the proper implementation of national policies and allowing institutions to protect, exchange and commercialize their own technologies, potentially generating revenues for further research and development. Globally, there is a steady decline in the financial support that governments provide to public institutions. In this declining environment, government policies around the world are shifting towards commercialization of agricultural research to help sustain public institutions. Policy makers and senior administrators are rethinking the ways in which technology from the public sector is handled and exchanged.

The capacity building at the institutional level needs to be addressed at three levels. First, IP protection needs to be institutionalized in relation to national policies. Secondly, persons responsible for the day-to-day handling of IPs should be well trained. Finally, scientists must be educated in the handling and management of IPs.

Currently, IP management lacks well trained people in developing countries. In order for institutions to function efficiently, human resources are essential. To help build capacity in IPR and technology transfer, the ABSP project, in cooperation with the Office of Intellectual Property at MSU, has organized an annual 1-week internship programme since 1996 (Maredia *et al*., 1996, 1997). The internship programme aims at providing hands-on experience with IP management on a day-to-day basis. The programme also covers how technologies are transferred from the public to the private sector. The emphasis in the internship programme is placed on the ideas, concepts and processes used in the handling, transfer and management of IPs by various US and international institutions. The participants' goal is to learn and become familiar with these ideas and return to their countries with this knowledge. During the last 7 years, over 100 international participants from over 20 different countries in Africa, Asia, Latin America and Europe have participated in the internship programme. This internship programme has been offered annually during the summer since 1996.

Institutional Development

Development of intellectual property management focal points

As discussed earlier, IP management lacks focal points in most developing countries. This requires establishing points of contact within public and private institutions that deal with IP management. Public institutions in the USA and other developed countries have gone through similar experiences and adjusted their policies and institutional framework accordingly. For example, in the USA, the passage of the Bayh–Dole Act in the early 1980s provided the basis for public sector IP protection and

technology transfer practices at universities. Taking advantage of these changes, public sector institutions reacted quickly and strengthened their IP protection and technology transfer framework through the creation of formal offices of IP and/or technology transfer. MSU, for example, established its Office of Intellectual Property in 1992. This office plays an active role in the day-to-day management of IPs. Indonesia, the Philippines and Egypt have recently established similar focal points (Maredia *et al*., 2000). IP/technology transfer offices' IPR management and technology transfer programmes (referred to hereafter as technology transfer office, or TTO) can play multiple roles in institutions involved in research and development. These multiple roles are described below.

Education and awareness

Arguably, the most important role of the TTO is creating awareness and educating scientists in how to handle new inventions and discoveries. The TTO can conduct educational programmes to make scientists aware of proper handling of inventions, including proper record keeping, use of confidential disclosures, publication guidelines and the development of proper agreements. The office can also conduct on-campus seminars and training programmes and develop informational materials.

Creation and modification of institutional policies related to intellectual property protection and technology transfer

The TTO can help to develop and enforce institutional policies dealing with inventions and discoveries. The office also ensures that the contractual requirements of funded projects are met.

Protection of intellectual property

TTOs play important roles when reviewing inventions and determining their patentability and commercial potential. For example, faculty members disclose their inventions to the TTO, which then works with appropriate legal and business personnel evaluating new discoveries and inventions. During this process, if found useful, the TTO can also help to protect and commercialize these new inventions. The TTO can also play a role in the event of infringement or litigation of IPs.

Generation of new revenues through licensing of intellectual properties

The TTO helps to assess the commercial potential of IPs and markets these technologies through licensing, thereby generating revenues. Licensing of technology involves promotion, marketing, negotiation, implementation and execution of the actual licence agreement, including collecting royalty payments. The office plays a key role in all of these aspects.

Networking

Networking is also an important role of the TTO. For example, if the office maintains a database of all new technologies with commercial potential, this information can be shared with potential commercial partners. Additional benefits include networking with other technology transfer associations and combining different technologies into technology packages. This combined package may create more value than a single technology alone and may enable execution of a licensing agreement.

Creation of new or start-up companies

The TTO, through links with venture capital firms, can help to establish new start-up companies using its own technologies by putting inventors, investors, attorneys and business managers together. Also, the office can help to educate researchers in what steps are required to start a new company.

Service to society

Because society supports many public institutions indirectly through the payment of state and federal taxes, sharing the benefits of new technologies is a service of the TTO office. For example, transferring a new food crop variety to farmers through links with the private sector rather than just giving it to a number of farmers may lead to greater distribution of the variety, which in turn leads to increased crop production and, perhaps, to lower food prices. Additionally, revenues generated through the licensing of technologies can support continued research and development of new technologies. Benefiting or serving society does not mean that new technologies are to be given at no cost or under no obligations; rather it is the dissemination of new technologies in a way through which the greatest number can benefit. In some cases this may mean providing a new technology at no cost; in other cases it may mean licensing the technology exclusively, which requires consumers to pay for the technology or what the technology produces.

Establishing an intellectual property/technology transfer office

Establishing a TTO is not an easy task. Issues that need to be addressed include institutional support for office operations, size of the office, the role the office will play and the development of an IP institutional policy. Continued financial support is critical for operating and managing the office. Experience in the USA and many other countries shows that, initially, these offices are not financially self-supporting and that the institution should provide operating funds until they become self-sufficient.

The size of the office includes the number of staff, the diversity and qualifications of personnel, and the size and location of the physical facility. In the USA, there are, staff-wise, both large and small offices, with small offices utilizing outside expertise as consultants on a needs-based basis. Large offices may have specialists in various disciplines that carry the technology from its first disclosure through to commercialization. MSU, for example, has a relatively small office with seven permanent staff members and it uses outside expertise, especially patent attorneys and business personnel. On the other hand, Texas A&M University has an office with more than 20 professionals covering nearly all aspects from invention disclosure to commercialization.

Regardless of office size, successful technology transfer requires the involvement of and/or interaction among technical, legal, business and financial personnel. The leader, director or coordinator of the office must establish a team framework and business plan to foster working relations and interactions among all these groups. Technical personnel may include broad areas of agriculture, basic sciences, engineering, medicine, etc. Legal personnel may include legal counsel, patent attorneys and infringement litigators. Business personnel include licensing and marketing individuals, with professional business liaisons. Financial personnel may include experts in venture capital generation.

In the USA, almost every public and private research institution has some form of IP protection and technology transfer operation. Many different names are given to these operations, including 'Office of Intellectual Property' (MSU), 'Technology Management Office' (University of Michigan), 'Office for Technology and Trademark Licensing' (Harvard University) and 'Technology Licensing Office' (Massachusetts Institute of Technology, or MIT). Regardless of the name, their roles are essentially the same.

Day-to-day function and operation of the office

Operation of TTOs varies depending on the size of the office, qualifications and roles of the personnel, the breadth of the office's mission and the size and location of the institution. The day-to-day operation would include many of the following elements:

- interacting with faculty, academic units, legal and business personnel;
- handling of inventions/disclosures and evaluation;
- protecting useful inventions and discoveries: material transfer agreements (MTAs), patents, copyright, trademark, trade secret, plant variety certification;
- maintaining patents, foreign filing;
- licensing and marketing of technologies;
- developing opportunities for new businesses or start-ups;

- designing and implementing institutional policies relating to the handling and management of IPs;
- conducting educational seminars, training courses and developing informational materials for education and awareness purposes; and
- networking with professional technology transfer organizations, industry and individuals.

Day-to-day operation of the Office of Intellectual Property at Michigan State University

MSU's Office of Intellectual Property (OIP) was established in 1992. The office handles IPs and inventions developed or created by MSU faculty, staff and students. The office is under the supervision of the Vice President for Research and Graduate Studies and is supported, in part, by the MSU Foundation, a non-profit entity. The OIP facilitates the commercial development and public use of technology developed by MSU researchers. The OIP obtains patents and then licenses them to private industry in return for royalties, which are shared with the inventors under university policy. The OIP's technology transfer programme has been one of the top ten in the country for the generation of royalties, with royalties of more than US$20 million per year. MSU licensees include large and small companies worldwide and a growing number of entrepreneurial ventures in and around Lansing, Michigan.

Currently, the OIP has seven staff members – including the Director, three licensing associates, one financial officer, one administrative assistant and one support person. The OIP assists researchers in protecting innovations and is MSU's negotiating and licensing agent in discussions with private industry. The OIP helps the MSU faculty to develop strategies for preserving the patentability of valuable ideas in light of publication and grant-application plans, and counsels the faculty on other patent-related questions. The OIP administers the university's royalty distribution policy and is authorized to sign confidential disclosure and MTAs, as well as patent documents, on the University's behalf. In keeping with commercial development goals of the State of Michigan, the OIP also helps entrepreneurial members of the MSU faculty or the outside community to establish start-up ventures based on MSU's platform technologies, and helps existing ventures to succeed by putting them in touch with Michigan resources and programmes.

According to MSU's policy, any inventions developed using MSU facilities, MSU funds or funds under the university's control are the property of MSU. These inventions are reported to the OIP. After the OIP has reviewed the disclosure with the inventor(s), a patent attorney is then consulted to review the invention for patentability. The patentability report is reviewed together by the OIP and the inventor. If the invention

is patentable, the potential commercial value of the invention is discussed. If the invention appears to have commercial value, the attorney is instructed to prepare a patent application and the OIP begins searching for an industrial partner or licensee. If all is successful, the industrial partner has a successful product, MSU receives royalties and society is benefited. Royalties are shared with the inventor, the inventor's academic department and MSU.

Under the ABSP project, MSU's OIP has assisted developing counties to establish MTAs and research agreements with both public and private sectors in the USA. Additionally, the OIP has contracted with legal experts to ensure that developing country partners' interests are represented in negotiations with the US public and private sectors. The OIP serves as the negotiating and licensing body for the university.

The OIP takes the lead in marketing MSU technologies, which includes implementing a system for non-proprietary descriptions of new technologies, locating potential licensees, conducting negotiations and, finally, licensing and policing these licences.

Interactions with the marketplace are facilitated by utilizing several mechanisms. These include active participation in technology transfer shows and meetings, computer networking through national and international database listings, and development of the OIP's own website at: www.msu.edu/oip

The office is also involved in entrepreneurial activities. Since its inception, the OIP has been involved in establishing more than 20 new companies based on MSU technologies. The OIP reviews the IP portions of various research agreements for the MSU Contracts and Grants Office when research proposals are submitted and joint venture agreements are issued.

The OIP is also involved in education. The office plays an important role by educating the MSU faculty, staff and international visiting scholars on IP transfer and management issues. Periodically, the OIP, in conjunction with other departments, holds joint seminars that provide information and training in IP handling. Finally, the office publishes and distributes information booklets on IP topics with titles including: *Inventorship*; *Protecting Your Invention, Handling Your Invention, Marketing Your Invention;* and *Should We Patent?*

Long-term benefits of having an intellectual property/technology transfer office

The long-term benefits of TTOs are enormous. Not only can the office assist in the protection of IPs generated within its institution, company or organization, but it can also serve as a platform for generating revenues for research and development activities. In addition, a new company

established through transfer of technology from the public sector to a private firm creates new job opportunities and enhances overall economic development. But most importantly it is able to take new technologies forward to benefit society.

The success of any IP office depends largely on how well the members of the technology transfer team interact with each other. A clear line of communication between the parties involved is essential. For the office to remain successful and competitive, the team members must establish a positive reputation.

Information Access

Appropriate information is key to IP use and management. Different parties require different types of IP information. Globally, as existing IP laws are modified to allow protection of agricultural technologies such as genes and plant varieties, availability and access to current, worldwide patent information is becoming very important. A concerted international effort is needed to assist developing countries in accessing information on patents and other IP-related information. Many institutions and programmes around the world provide IPR and technology transfer-related information and offer educational opportunities (see Appendix 4.1).

Since ABSP began, the project has helped access information through various means (ABSP, 1997; Ives *et al.*, 1998; Maredia *et al.*, 1999). Individuals from the collaborating countries have been able to access information through participation in ABSP-sponsored workshops (Maredia and Bedford, 1994; Maredia, 1995) and internship programmes (Maredia *et al.*, 1996) and meetings of professional organizations such as AUTM and BIO (see Appendix 4.1). Additionally, ABSP has helped to establish internet-based services including e-mail and a website (www.iia.msu.edu/absp). The project has also published Linkages, an electronic newsletter distributed to scientists, administrators, policy makers and the donor community all over the world. Through these means, communication and networking within the biotechnology community were greatly enhanced. Most recently, ABSP produced an IP workbook that provides an IP base from which those new to IP management activities can understand the basic principles for the management of IPs (Erbisch, 2003).

Future Directions in Capacity Building in Intellectual Property Rights

Capacity building in IP management is complex. These complexities require regional and global cooperation. IPR and technology transfer issues related to agricultural biotechnology are still evolving. Countries

around the world are trying to learn from each other and build their capacity to manage IPs. Developing countries may learn from the experiences of developed countries. Capacity-building success in any country will largely depend on how the parties involved in these complex issues communicate and work together. Addressing IPR issues and human resource development is critical. It is hoped that the developed nations, with their wealth of IP management experience, will assist developing countries so that true global interdependence can be achieved.

ABSP, MSU and the OIP, through IP management specialists, have provided basic IP management training for several hundred individuals from developing countries. These efforts have been facilitated through annual week-long short courses at MSU, through in-country workshops, through participation in seminars sponsored by developing countries and through in-office (OIP) internships. It is expected that these efforts will continue, even after ABSP leaves MSU. What has become most evident is that, while these efforts have been very successful, much more is needed to continue developing IP management capacity around the world.

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APPENDIX 4.1. Selected Institutions and Organizations that Offer IPR-related Information, Training and Networking Opportunities

International organizations

International Union for the Protection of New Varieties of Plants (UPOV)
www.upov.int

World Intellectual Property Organization (WIPO)
www.wipo.org

World Trade Organization (WTO)
www.wto.org

Societies and associations

Association of University Technology Managers (AUTM)
www.autm.net

Licensing Executive Society (LES)
les.org

Technology Transfer Society (T2S)
millkern.com/washtts/docs/national.html

Education

World Technology Access Program (WorldTAP)
www.iia.msu.edu/worldtap.htm

Franklin Pierce Law Center
www.fplc.edu

Strategic World Initiative for Technology Transfer
www.swiftt.cornell.edu

United States offices

USDA Plant Variety Protection Office
www.ams.usda.gov/science/PVPO/pvp.htm

US Copyright Office
www.copyright.gov

US Patent and Trademark Office
www.uspto.gov

Informational organizations

AgBiotechNet
www.agbiotechnet.com

bioDevelopments
www.bioDevelopments.org

GlobalEDGE
www.globalEDGE.msu.edu

International Service for the Acquisition of Agri-biological Applications South East Asia Center (ISAAA) (Crop Biotech Update)
www.isaaa.org/kc

International Service for National Agriculture Research (ISNAR)
www.cgiar.org/isnar

UNDP Civil Society Organizations and Participation Programme: Conserving Indigenous Knowledge
www.undp.org
www.undp.org/csopp/CSO/New Files/dociknowledge.html

5

Plant Variety Protection in the USA

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Introduction

Development of a new plant cultivar or variety, either by 'traditional' breeding methods or by 'modern' molecular modification, requires a large input of time and effort. Some companies estimate that it takes 10–15 years to develop a new variety. In order to speed up this process, companies use winter breeding sites and genetic manipulation. Although these practices may produce new varieties faster, they also increase costs. To recover the costs of research and development, the breeder may seek to obtain exclusive marketing rights for the new variety. Various ways of doing this exist, such as keeping trade secrets, or obtaining plant patents, utility patents or plant breeder's rights (plant variety protection or PVP). This chapter will focus on the plant variety protection system in the USA.

The UPOV Convention

In 1961, several European countries decided to form a treaty organization dealing with plant breeders' rights (PBR). They called this organization the International Union for the Protection of New Varieties of Plants, which is known by its French acronym, UPOV. The treaty, or Convention, was amended in 1972, 1978 and 1991, as members acquired experience with the system. Interesting information concerning the history of this organization, and copies of all versions of the UPOV Convention, can be found on their website (www.upov.int/eng/index.htm). The 1991 UPOV Convention became effective in 1998, when it was ratified by a sufficient number of countries.

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The UPOV Convention defines which genera and species are covered, the conditions for granting breeder's rights, how to make an application, what rights are granted to the breeder, how to name varieties, how to become a member of UPOV, obligations of the members and other administrative details. The UPOV Convention is not a law but a treaty that establishes principles and definitions agreeable to its members to ensure that the laws in each country are similar to each other. Member countries must enact their own laws to put these principles into effect for themselves. Once their law is in place, they can become a member of UPOV. From its beginnings in 1968 with only three members (Germany, The Netherlands and the UK), UPOV has grown to include 51 member countries. Thanks to the Convention on Biological Diversity (www.biodiv.org/) and the GATT Agreement on Trade-related Aspects of Intellectual Property Rights (commonly known as the 'TRIPS' Agreement) (www.cerebalaw.com/gatttext.htm), approximately 100 more countries are interested in becoming members in the near future.

The 1991 UPOV Convention made several significant changes. All genera and species are to be eligible for PBR. The rights granted were extended to include importing, exporting, conditioning and stocking the variety. The materials covered by the rights include harvested materials of the variety, products made from harvested materials and essentially derived varieties. The length of protection was extended. These changes strengthened the rights granted to plant breeders.

DUS Testing

The main principle of UPOV is that breeders be granted exclusive marketing rights for a limited time in order to recover the costs of developing new plant varieties. To qualify for these marketing rights, the new plant variety must be distinct, uniform and stable (DUS). The general procedure is that the breeder files an application in a UPOV member's PBR Office. With the application, the breeder provides seeds. These seeds are used by the PBR Office to do 2–3 years of testing. The data collected from these tests are used to determine whether the plant variety meets DUS standards. If DUS is established, then the breeders' rights are granted. The rights only cover actions done within the country where the rights were granted.

In order to get PBR in other countries, the breeder must file applications and pay fees in each additional country. Each country must determine whether DUS is established according to their law. Some countries cut costs and save time by sharing the data they collect during DUS testing. European countries have developed an extensive system of cooperative testing. For example, all maize tests are done in France. If the breeder wants to get PBR for the same maize variety in another cooperating country, the

DUS tests will not need to be repeated. The results of the French testing can be used in support of maize applications in several other countries.

Prior to formation of the European Union (EU), a breeder needed to file applications in many countries and pay many fees to ensure that the breeder's rights would be recognized when the plant was sold internationally on the European continent. Now that the EU has formed, filing the application with the EU PBR Office (PBRO) has simplified this procedure. Rights granted by the EU PBRO are recognized by the 15 EU member countries.

Another variation in DUS testing is the use of breeder-generated data. For example, the Australian PBRO allows the breeder to conduct 1 year of tests under strict test guidelines and with inspections of the trials. The PBRO also does 1 year of trials. If the results of the breeder's DUS trial agree with the results from the PBRO's DUS trial, then no further testing is required. If the two trials do not agree, then the PBRO conducts a second year's DUS trial. This system has the potential to shorten the time between filing the application and granting the PBR. Several other UPOV members utilize breeders' data including the USA as will be described below.

History of Intellectual Property Rights in the USA

Many people are confused about intellectual property rights (IPR) in the USA because we have so many options. Most of these options can be explained by the history of IPR in the USA. The first US patent was issued in 1790 (www.uspto.gov). Because they have been around for so long, most people understand what patents are and how they work, at least in a general sense. In contrast, most people are unaware of the PVP Act.

As early as the 1890s, fruit and tree breeders noticed that clever customers could easily take new plant introductions and reproduce them through cuttings, grafts or other asexual methods and then they could sell the same plants themselves. When these breeders wanted protection for plant 'inventions', they turned to the Patent Office to have their plants protected by patents. This led to the passage of the Plant Patent Act of 1930, which allowed for patenting of asexually reproduced plants (except tubers). This form of protection is used by breeders of trees (such as fruit, citrus and nuts), shrubs (such as azalea and viburnum), ornamentals (such as chrysanthemum, rose and impatiens) and fruits (such as blueberry, grape, raspberry and strawberry).

Tubers and seed-reproduced crops were excluded from the Plant Patent Act. These crop types include our major food crops. Seed-reproduced plants were believed to be non-uniform and unstable, and therefore ineligible for patents. By the 1960s, some European countries enacted PBR laws under the 1961 UPOV Convention. They were able to show that

sexually reproduced varieties could be made to be uniform and stable enough to be included in these laws. During the 1960s, several attempts were made to enact similar protection in the USA, including a proposal to revise the Plant Patent Act to include sexually reproduced plants. These early attempts were unsuccessful. The American seed trade then turned to the Department of Agriculture to draft new legislation for seed-reproduced plants. The Plant Variety Protection Act was enacted in 1970.

Some crops were excluded from protection in the 1970s. Protection for okra, celery, peppers, tomatoes, carrots and cucumbers was added in 1980. The USA joined UPOV in 1981 under the 1978 UPOV Convention. In 1994, the US PVP Act was amended to comply with the 1991 UPOV Convention, which expanded protection to all plants. At that time, tuber-reproduced plants were specifically added to the scope of eligibility and an exclusion against F_1 hybrids was removed.

As noted in Chapter 2, various interpretations of patent law have been made, especially Diamond v. Chakrabarty (447 US 303 [1980]) and *Ex parte* Hibberd (227 USPQ 443 [1985]). Now seed-reproduced plants can be protected under the general patent law. These patents are also known as 'utility patents', since the invention must demonstrate its usefulness. It is possible for a seed-reproduced plant to obtain both a utility patent and a PVP certificate (J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred International, Inc. 534 US [2001]).

Administration

The Patent and Trademark Office is responsible for administration of plant patents, utility patents and trademarks. Copyrights are handled by the US Copyright office. They are organized within the Department of Commerce and have over 6500 employees. The Patent Office issues over 180,000 patents per year (www.uspto.gov).

The PVPO is responsible for administration of the PVP Act (PVPA). It is organized within the Agricultural Marketing Service of the US Department of Agriculture. Currently, there are 10 people on the PVPO staff. The Commissioner is the head of the staff, which includes clerical personnel, a computer specialist, examining assistants and plant variety examiners (www.ams.usda.gov/science/PVPO/pvp.htm).

Workload

Each PVP examiner is responsible for handling applications of specific crops (see the distribution of crops given in Appendix 5.1). The examiner develops expertise in handling applications of their assigned crops. This expertise leads to more efficient examining of the crops.

Each PVP examiner gets an approximately equal share of the number of new applications filed each year. Between 1989 and 1995, the PVPO received 300 new applications per year. Between 1996 and 2000, immediately after the 1994 amendments were enacted, the number of applications filed each year increased to 400. Since 2000, the number of new applications filed each year has returned to its previous level of 300 applications per year.

Analysis of Applicants

Of the 300 new applications received in the PVPO each year, close to 1% are for ornamental crops and about 6% are for tuber crops. Agricultural crops make up 75% of applications and vegetable crops account for 18% of applications. Only 27 applications for first-generation hybrids have been received, in bermudagrass, broccoli, sweetcorn, muskmelon, pepper, sunflower, tobacco and tomato.

Seventy-four per cent of our applicants are US citizens or companies. An additional 15% of applicants are from public institutions, such as universities or government agencies. Only 11% of our applications are received from non-US citizens or companies.

Five per cent of applicants file 40% of the PVP applications. These applicants tend to be more experienced in how to prepare a PVP application and their applications have few errors or omissions. This means that their applications can be finalized quickly. Sixty-seven per cent of applicants file only one or two applications per year. These applications tend to have more errors or omissions, which need more than one request for additional information before the application can be finalized. It often takes twice as much time to finalize one of these applications.

Eligibility of the Applicant

A breeder of any sexually reproduced or tuber-propagated plant variety may apply for PVP. Although breeding work is done by persons, the law recognizes that persons working for a company may not have ownership rights over the variety. Often an employee will have an agreement with the company that states:

> By agreement between the employee and [the company] all rights to any invention, discovery, or development made by the employee while employed by [the company] are assigned to [the company] with no right of any kind retained by the employee.
>
> (J.C. Robinson Seed Company, 2000)

In these cases, the company is recognized as the owner of the variety and is listed as the applicant. The agreement between the breeder and the company should be described as part of the application's Statement of the Basis of the Applicant's Ownership, which is described below.

Another requirement for eligibility of the applicant is the nationality of the owner/applicant. All US citizens and residents and US companies are eligible to apply for PVP. The PBR laws of UPOV member countries allow for citizens of the US to obtain PBR equivalent to the rights that the US would grant under the PVPA. Therefore, citizens, residents and companies of UPOV member countries are eligible to apply for PVP in the USA.

Citizens of countries that are not UPOV members but have *sui generis* laws that grant intellectual property rights to plant varieties can also apply for PVP in the USA. They must first demonstrate 'reciprocity'. In essence, this means that what your country will do for US breeders, we will do for your breeders. When the application is filed, the applicant must also provide a copy of their country's PBR law, translated into English. The PVPO will study this law to see what rights could be granted to US citizens under that law for the same genus and species. The non-US, non-UPOV applicant would then be granted only those rights that their law and the US PVPA have in common. Recently, the Thailand Department of Agriculture filed an application in the USA. The applicant submitted a translation of the Thai law in order to establish reciprocity with the USA (T.A. Salt, Maryland, 2002, personal communication).

Eligibility of the Plant

The requirements of protection are that the variety be new, uniform, stable and distinct from all other varieties. All information used to determine whether a variety meets these criteria is gathered and reported by the applicant to the PVPO. Site visits are not required. PVP examiners base their decisions on the descriptive information and trial data supplied by the applicant. Clarifying or supplementary data may be requested from the applicant during the course of the examination. This may require that the applicant conduct additional trials or tests or provide live specimens.

In order to be considered new, a variety may not have been sold or otherwise disposed of for more than 1 year in the USA or for more than 4 years in a foreign country (or 6 years in a foreign country in the case of trees and vines). Actions that may meet the definition of 'disposed of' include granting of PBR, listing the variety on an official register of varieties, making the variety publicly known or a matter of common knowledge through publication or advertisement, or any other activity that

indicates the existence of propagating or harvested material of the variety. Sale or disposal of hybrid seed is considered to be sale or use of the parental lines (Lubrizol Corporation, 1992). This must be considered when dealing with certain crops, such as maize. Exceptions are allowed for varieties while they are undergoing testing or experimentation.

How to Apply for PVP

To request protection for a new variety, the applicant completes an application form (see Appendix 5.2) and an application packet. The complete packet must contain the following items: the fees, a seed sample, Exhibits A, B, C and E. Exhibit D is optional.

The applicant may designate a person to serve as the representative. The representative is the one person to whom all correspondence from the PVPO is sent and from whom all responses will be accepted. The representative must be authorized or revoked in writing. Many applicants do not appoint a representative, but represent themselves. If one is appointed, applicants usually choose the breeder to serve as the representative since the questions asked by PVP examiners often concern the breeding history, trial data or specific traits of the variety.

Application Form

The application form identifies the applicant/owner and the variety. Contact information for the applicant and the representative are given on this form. The variety is named, its botanical classification (family, genus and species) is given, and the common name for the crop is given. Taxonomic information can be found on the Germplasm Resources Information Network website (www.ars-grin.gov/npgs/tax.index.html).

Variety names must be unique and meet certain standards. The Federal Seed Act is the legislation that governs the naming of agricultural or vegetable plant varieties. It is enforced by the Seed Regulatory and Testing Branch, which is the naming authority in the USA. For those crops not covered by the Federal Seed Act, it is suggested that applicants follow the International Code of Nomenclature for Cultivated Plants (Trehane *et al.*, 1995) and register the name with the appropriate International Cultivar Registration Authority. An affidavit or letter stating that the variety name is acceptable to the appropriate naming authorities should accompany the application packet.

The applicant has the option to request that seed be sold only as a class of certified seed. Certified seeds must meet specific standards for purity, germination, noxious-weed seeds content and moisture content. The Federal Seed Act Regulations and Rules of Practice set the standards

for classes of certified seed. The Seed Regulatory and Testing Branch is accredited by the International Seed Testing Association and recognized as an unbiased authority for conducting tests on samples. If the applicant chooses to sell the variety only as a class of certified seed, that choice cannot be reversed. This decision can be delayed until the certificate is ready to be issued.

If the variety has been sold or disposed of, the applicant must report when and where the variety was first released. This information is used to determine whether the variety is new. If the variety was released under special circumstances, the applicant should explain the circumstances so a correct decision can be made.

Because dual protection from patents and PVP are possible and can affect future use of the variety, it is appropriate for applicants to indicate other forms of IPR that protect the variety. This includes PBR applications filed or granted in other countries, plant patents, utility patents, trademarks or other IPR. This serves to notify the public about other rights that the applicant intends to enforce.

The application form needs to have an original signature from either the applicant or the representative. This signature attests to the truthfulness of the data and the claims made in the application.

Fees

The PVPO is completely user-fee funded. All operating costs are recovered by the fees collected for services. When filing an application, the applicant must pay the fees for filing the application and for conducting the search. Fees cannot be paid electronically, so payment must be made by check or money order, made payable to the 'Treasurer of the United States'. The fee schedule changes periodically and is published as part of the Regulations and Rules of Practice under the PVPA. Currently the costs of filing, examination and issuance total US$3025.00. A fee increase to US$4084.00 was proposed on 1 October 2002.

Seed Sample

Applications must be accompanied by 2500 viable, untreated seeds to serve as the voucher specimen. The sample is stored at the National Center for Genetic Resources Preservation (NCGRP) in Ft Collins, Colorado. The NCGRP requires a phytosanitary certificate for seed samples that are imported into the USA.

While the application is being processed and after the certificate is issued, the seed sample is controlled by the PVPO. If the application is abandoned or withdrawn, the applicant is given an opportunity to say

what to do with the seed sample: destroy it, return it to the applicant or transfer it to the NCGRP's regular collection. After the certificate is issued, the applicant no longer has these options, since the seed sample belongs to the PVP and ultimately to the public. When the certificate expires, is abandoned or withdrawn, the seed sample is transferred to the NCGRP's regular collection.

Seed samples sent to the PVPO in support of an application for protection are voucher specimens. A written description of a plant variety is not complete, since the technology to describe and identify plants is constantly changing. If a question ever arises about the characteristics of a variety that has PVP, we could go to the voucher specimen and confirm the variety's characteristics through a grow-out trial or genetic fingerprinting. This type of confirmation was needed in an infringement case, where the sample was supplied to a third party under court subpoena. Another release occurred when a certificate holder wanted to change the varietal description and needed to demonstrate that the change was retroactively accurate.

The issuance of a certificate does not always mean that the seed is available. Most varieties granted a PVP certificate are sold as seed by the owner of the variety and are available through regular marketing channels. Some varieties are granted a PVP certificate but are used as parental lines for hybrids. The variety *per se* is not available in this case. On at least one occasion, a company wanted to get seed of a protected variety. It was not available from the owner, so the company asked the PVPO to give them a sample of the voucher specimen. The request was denied, since their intended use of the sample was not to confirm the characteristics of the protected variety.

The applicant may be asked to replenish this sample if the germination rate or sample size falls below adequate levels during the protection period. The germination rate needs to be 85% or greater when the sample is received. Studies have shown that seed samples that germinate at this level will maintain some viability over the 20-year term of protection. The sample is retested at regular intervals. If the germination rate falls below 85% or if the number of seeds falls below 2100, then the NCGRP requests that the seed sample be replenished.

Seed sample requirements for tuber crops or first-generation hybrids are slightly different from those for other kinds of crops. The voucher tissue sample of a tuber will be requested when the certificate is ready to be issued. At that time, the deposit procedures and associated costs will be sent to the applicant. With the application, the applicant should send a document that states that a tissue sample will be deposited before the certificate issues. Seed samples for first generation hybrids need to include seed of the hybrid and seed of all parental lines needed to propagate the variety. If maintainer lines are needed to propagate the variety, then they also need to be supplied with the seed sample.

Exhibit A: Origin and Breeding History

We check Exhibit A to determine whether the applicant meets the definition of breeder and that development of the variety was carried out by the applicant. If the applicant has discovered but not developed the variety, then the variety is not eligible for PVP. Specifically, the applicant needs to describe the complete breeding history, tracing it back to commercially or publicly available lines, varieties, populations, etc. The breeding history also includes the methods and intermediate steps taken during the breeding of the variety, what traits were used as selection criteria at each stage of selection, what breeding methods were used, how many generations of inbreeding and roguing were performed and other details of multiplication.

In order to establish that the variety is uniform and stable, the applicant needs to include three statements within Exhibit A. The first statement is whether there are genetic variants that are to be expected during normal maintenance of the variety (not off-types, which derive from external contamination). If variants are expected, then the description of the variants and their frequency should be stated. If there are no variants this must be stated. If the frequency of variants is greater than 5%, then the stability and uniformity of the variety is questionable. The 5% level was decided upon based on standards set in the Federal Seed Act for seed lot purity.

The second statement concerns whether the variety is uniform. Details within this statement should indicate whether all plants in the population look the same and how this conclusion was reached.

The third statement concerns whether the variety is stable. This statement should include the number of generations over which the variety was observed to determine that all traits of the variety are maintained over generations. More than one generation of observation is needed to establish stability of the variety.

Exhibit B: Statement of Distinctness

The variety must be clearly distinguishable from all previously existing varieties. A clear difference may be based on one or more identifiable characteristics. The applicant's claims for distinctness are presented in Exhibit B. Since the US PVPO does not perform grow-out trials, applicants need to gather and report all information that is required to complete the application.

Some people ask: how can we trust the data provided by the applicant? Are we not afraid that they will misrepresent their variety in order to get protection? The answer to these questions has three parts. First, the applicant must sign the application form. By doing this, the applicant is

signing a legal document. If we later discover that false information was given, we can nullify their certificate. Secondly, if a customer finds that the information is misleading or harmful, the customer may sue the owner of the variety. Certainly, the customer will stop buying the variety. Thirdly, universities conduct independent trials for many of the major crops. The characteristics of the variety are published and we incorporate them into our databases. If the independent trial data does not match the description provided by the applicant, then we can question them about these discrepancies when we examine the application. By using these three areas, we feel that we can successfully use breeders' data without needing to visit their trial sites.

The simplest way to present distinctness is to name one variety that is 'most similar' to the application variety in genetic background and morphology. Other methods are acceptable but more difficult to carry out, such as: (i) naming the group to which the variety belongs, naming all varieties in the group and describing, one at a time, how the variety differs from each variety in the group; or (ii) naming all varieties in the crop and describing, one at a time, how the variety differs from each.

In order to verify that the comparison variety is really the most similar variety, we need to have a complete description of the comparison variety. The applicant needs to provide the description of the most similar comparison variety, if one is not already on file in the PVPO.

After this comparison statement is made, the applicant needs to contrast the application variety with the variety to which it is most similar, citing specific character states to support the contrasts. Differences in quantitative characters (such as maturity, plant size, leaf size and flower size) between the variety and its most similar comparison varieties must be given as numerical data obtained from paired comparisons with statistical tests showing degree of significance. Colour differences should be referenced with a standard such as the *Munsell Book of Color* or *Royal Horticultural Society Colour Chart*. Complex traits, such as yield, are not useful in establishing distinctness. However, traits that contribute to yield (fruit weight, fruit size, number of fruits per plant, etc.) may be used to establish a clear difference. Colour photographs (prints) showing the contrasting traits of both the variety and its comparison variety should also be included. In order to make meaningful comparisons with the data we have available, at least 1 year of trials should be conducted in the USA in a region where the variety will be grown.

Exhibit C: Objective Description of the Variety

Exhibit C is the Objective Description of the variety using forms created by the PVPO. Breeders and other knowledgeable persons are consulted before a draft form is finalized. These forms are used to standardize a com-

plete botanical description of the variety, making it easier to determine differences between varieties. The form should be completely filled in unless a particular character has no relevance to your crop kind. Newer forms may have room for descriptions of the application variety and a comparison variety, plus simple descriptive statistics and colour chart values. When reviewing Exhibit C, we ask ourselves several questions.

1. *Is the variety description complete?* Although the voucher seed sample is the most complete description of the variety, Exhibit C is the official written description of the variety. It will be used to establish the distinctness of this application and it will be used in the future to ensure that future varieties are distinct from previously existing varieties. It is important that the description be as complete as possible to help in these efforts. When others want to know how a protected variety looks, they request a copy of Exhibit C. Interested persons have included competing companies, seed certifying agencies, farmers and accused violators.
2. *Is the variety description consistent with other data presented in the application? Is it consistent with other descriptions found in the literature?* If the Exhibit C data conflict with other descriptive information, we question the uniformity and stability of the variety. If the Exhibit C data conflict with data used to support distinctness, the distinctness may not be clear. Since our forms have several characteristics that may be influenced by environmental conditions, we must be aware of these traits and the range of variability that is expected for a uniform and stable variety. Any questions may warn that DUS has not been established.
3. *Has the applicant collected the data and reported it using appropriate methods? Are any data values 'wrong'?* We can use the seed sample to check for correct values about seed size and colours, and we have found some mistakes by doing this. Other problems we have noted are: the value is outside the normal range for the trait (the applicant reported inches rather than centimetres); the verbal colour did not match the colour chart value (the applicant did not understand how to use the colour chart or when to read the colour); typographical errors (missing decimal points or transposed numerals).

Exhibit D: Additional Description of the Variety

Exhibit D is optional and can include anything not included elsewhere in the application packet. Information in this section may include test-cross results, trial data, isozyme or other molecular test results, photographs, possible uses for the variety or its products, specific descriptive information not disclosed elsewhere in the application or anything the applicant feels may be useful. This section may be omitted if the data are placed in another Exhibit.

Exhibit E: Statement of the Basis of the Applicant's Ownership

Exhibit E should describe how the applicant obtained ownership of the variety and whether anyone else can claim any rights regarding this variety. This document helps us to determine that the original breeder and the applicant, if they are different, are eligible to apply for protection in the USA. Please refer back to the section on eligibility of the applicant, discussed above.

How Applications are Processed

Once the applicant has submitted a complete application (application form, Exhibits A, B, C and E, fees and seeds) to the PVPO, the application is given a PVP application number and a filing date. The filing date is used to determine priority in case of protests. The application is assigned to a PVP examiner.

The PVP examiner conducts a literature search of the crop and gathers descriptive information on varieties from grow-out trials, release notices, seed catalogues, PVP applications and other published sources. The examiner maintains the variety descriptions in computerized crop databases. Over 75,000 different varieties in more than 170 crops are currently in the system. The examiner then uses the appropriate database to determine the distinctness of the application variety.

The description of the application variety (from the Exhibit C form) is entered into the database. A stepwise Boolean search (query) is performed to help determine distinctness. Each time we ask a question, we hope to reduce the number of matches that the computer finds, until, ideally, we find that only one variety – the application variety – remains as a match to all conditions listed in the search.

These search criteria are not 'point' values, but values in a reasonable range surrounding the value reported. This helps to account for environmental influences. Small differences between varieties may not be adequate to distinguish among varieties. For example, we cannot distinguish 'intermediate' from either 'low' or 'high', but we can distinguish 'low' from 'high'. If an excessively high variability is reported for a trait, then we widen our search range. Sometimes we must widen the range to the point where the trait becomes useless for establishing distinctness.

If questions arise during the examination of the application, the examiner corresponds with the applicant. Questions may be raised concerning data conflicts, uniformity and stability, inadequate statistical support for distinctness, or the existence of varieties that are indistinguishable from the application variety (based on the results of the search

of the crop database). The applicant is asked to provide additional information. This information (with supporting evidence) may come from prior knowledge or from additional grow-out trials.

Issuance of PVP Certificates

When the examination is complete, the PVP examiner summarizes the process and its results. If the variety is found to be eligible for protection, then the PVP examiner recommends this to the Commissioner. The Commissioner verifies the findings of the PVP examiner and writes to the applicant requesting that the certificate issuance fee be paid.

The certificate order form is sent with the request for payment of the issuance fee. It indicates the variety name and owner's name that will be printed on the PVP certificate. If any changes need to be made, they should be made prior to issuance of the certificate. For example, if a temporary variety name was given at the time of filing, an approved permanent variety name must be provided before the certificate can be issued. If the name of the owner is spelled incorrectly, it should be corrected on the certificate order form. Also, if not yet designated, the certificate holder may specify that the variety be sold only as a class of certified seed, as discussed above. Once specified, the designation cannot be reversed later.

The final certificate is signed by the Commissioner and the Secretary of Agriculture, is bound with a green ribbon and is embossed with a golden seal of the PVPO. Within the text, it states the length of protection and what rights have been granted to the certificate holder. Inside the certificate, a copy of the application papers is permanently riveted to the certificate.

Analysis of PVP Productivity

Since 1971, over 5200 PVP certificates of protection have been issued in over 170 crops. PVP certificates were originally issued for a 17-year term of protection. This was increased to an 18-year term of protection in 1981, and is now a 20-year term for most crops or a 25-year term for trees or vines. The term of protection starts when the PVP certificate is issued and is specified on the face of the certificate. The term of protection cannot be extended. Over 1300 certificates are no longer in effect due to being abandoned, cancelled, expired or withdrawn.

Applications are processed in the order in which they are received. Historically, the PVPO has been able to process 77% of the applications (from receipt to issuance of a certificate) in less than 36 months. The most difficult case took 10 years to process. The total time needed to process

an application depends on the amount of research needed to create or maintain the crop database, the completeness of the application packet and the ease of distinguishing the application variety from all other varieties of the crop. Eligibility and procedural requirements may also cause delays, thus lengthening the examination period.

We currently (2002) have 975 applications pending a final decision. In fiscal year 2001, we finalized 613 applications, including those PVP certificates that were issued (495) and those applications that were abandoned or withdrawn by the applicant (117), or denied or declared ineligible by the PVP examiner (1). At our current rate of processing applications, we have a 1.5 year 'backlog' of applications.

Rights Granted

Once granted, the applicant may exclude others from selling or marketing the variety, conditioning or stocking the variety, offering it for sale or reproducing it, importing or exporting it, or using the variety to produce (as distinguished from develop) a hybrid or different variety, or any other transfer of title or possession of the variety. Certificates of protection are effective for 20 years (25 years for vines and trees) from the issuance of the certificate.

These rights extend to essentially derived varieties, indistinct varieties, harvested materials and varieties that require repeated use of the protected variety. There is an exemption that allows farmers to save seed of the protected variety for use on their own farm (Asgrow Seed Co. vs. Winterboer 513 US 179 (1995)), but this exception does not allow the farmer to transfer ownership of the saved seed to another person for reproductive purposes. Researchers also have an exemption so that the protected variety can be used in plant breeding or other research.

A certificate holder has certain responsibilities. The seed sample must be replenished when requested. The PVPO must be informed of changes to the address of the certificate holder, or the person who is authorized to act on the certificate holder's behalf. The variety name must be used even after the certificate expires. The version of the PVPA under which the certificate was issued must be included on all labels. The certificate holder must also notify the public that the variety is protected, using appropriate language.

Essentially Derived Varieties

In a typical breeding programme, a breeder uses previously existing varieties as the genetic basis for a new variety. Depending on the methods used, the new variety may be very similar to one of the parent vari-

eties. When this happens, the new variety is described as 'essentially derived' from the parent variety, meaning that a large percentage of the genetics of the new variety come from that one parent. This is a biological reality that has existed for years. For example, for a variety that was male sterile, a related variety could be created by backcrossing the restorer gene, or for a variety that was susceptible to *Helminthosporium maydis*, a related variety could be created by backcrossing the gene for resistance to *H. maydis*.

In the 1991 UPOV Convention, essentially derived varieties (EDVs) acquired legal standing. If the parent variety is granted PBR under the 1991 UPOV Convention, then the owner of the parent variety would have rights over varieties that are essentially derived from it. Although this has never been tested in the courts, the American Seed Trade Association and UPOV subcommittees are working to more clearly define when a variety is essentially derived. For example, the percentage of the genetics that must be shared to qualify as an EDV seems to depend on the crop.

The PVP examiners do not consider whether a variety is an EDV during the examination. To prove distinctness, only one clear difference between the varieties is necessary. If both varieties are new, distinct, uniform and stable, then both varieties could receive a PVP certificate. The details of the breeding history in Exhibit A could be used by others to determine whether the new variety is essentially derived from another variety.

Biotechnology and PVP

There is no prohibition against genetically modified plants in the PVPA. Therefore, the background of the variety does not determine whether it is eligible for PVP. The variety must demonstrate that it is new, distinct, uniform and stable. If the development of the variety was accomplished by insertion of a gene, then it should be easy to demonstrate the distinctness of the variety by citing the gene insertion and functionality of the gene in the variety.

A genetic test may be used to establish the distinctness of the variety. For example, differences may exist in the presence or absence of isozymes, restriction fragment length polymorphisms, simple sequence repeats or other genetic fingerprinting techniques. The technique should be carried out using published methodology and publicly available enzymes and probes. In order to be a clear difference, the results must be repeatable so that the differences between the varieties can be demonstrated over and over again. Also, the variety must be uniform and stable enough that the differences can be demonstrated repeatedly.

Other UPOV members are reluctant to use a genetic fingerprinting technique as the only means of differentiating the application variety from previously existing varieties. Their main concern is that the difference is not clear and that it does not meet minimum distance standards. If the difference is based on the banding pattern on an electrophoresis gel, is a one-band difference enough to distinguish the variety, or should two or more bands be required? They argue that, if a genetic fingerprinting technique is used to establish distinctness, that portion of the genome must be linked to a morphological or physiological trait. Large portions of the genome are non-coding, junk DNA. What if the band that is chosen is from a non-coding portion of the genome? Should it be allowed to serve as the only difference between varieties? Since they are non-coding, any point mutations would be non-lethal to the plant. Non-lethal mutations could accumulate over time and make it impossible to repeat the test and re-establish the distinctness of the variety. Does this not also point to the lack of stability and uniformity of the plant variety? These types of questions have been asked for many years and will continue to be the source of lively discussions for years to come.

Conclusion

Plant breeding is a dynamic industry, mingling the old methods with new technology to its best advantage. The PVPO also mingles the old and new methods when determining the uniqueness of a plant variety. Their effectiveness shows in the growth of the breeding industry since 1970.

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Appendix 5.1. Plant Variety Protection Office crop distribution list, September 2002.

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Agrotricum
Atra Paspalum
Bahiagrass
Basil
BEET/CHARD
Bluestem
BROMEGRASS / Rescuegrass
BUFFALOGRASS
Chicory
CLOVER
COTTON
COWPEA
Crownvetch
Dogstail, Crested
ENDIVE / Chicory
FENNEL
Flaccidgrass
Foxtail
Gamagrass
Hardinggrass
Lespedeza
Lovegrass
Milkvetch
MILLET
Molassesgrass
OKRA
ORCHARDGRASS
PARSLEY

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CANOLA (Rapeseed)
SOYBEAN

Mark A. Hermeling
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ALFALFA
BARLEY
BEAN, PHASEOLUS
BEAN, LIMA
Bean, Mung
Chickpea
LENTIL
LETTUCE
OAT
PAPAYA
PEA
RYE
SORGHUM/SUDANGRASS
TOBACCO
TOMATO
TRITICALE

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Alkaligrass, Weeping
BENTGRASS
BERMUDAGRASS
BLUEGRASS
BUCKWHEAT
CAPER SPURGE
Castorbean
CELERY
CENTIPEDEGRASS
CHRYSANTHEMUM
FESCUE, FINE LEAF
FESCUE, TALL & MEADOW
Festulolium Tanden
FLAX
Florida Fingergrass
Hair-grass, Crested
Kleingrass
LAURISAGRASS
Japanese Lawngrass
Manna Grass
MEADOWFOAM
Mustard, White (use rapeseed)
ONION
PEANUT
Primrose, Evening
RICE
RYEGRASS

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ARTICHOKE
Asparagus
ASTER, CHINA
BROCCOLI /RAAB
CABBAGE
CALENDULA
CARROT
CAULIFLOWER
COCKSCOMB
COLEUS
COREOPSIS
CORN, FIELD/POP/SWEET
COSMOS
CUCUMBER
DAHLIA
DAISY
DELPHINIUM / Larkspur
EGGPLANT
GAZANIA
KOCHIA
LOBELIA
LUPIN
MARIGOLD
MUSKMELON/HONEYDEW
NASTURTIUM
NIEREMBERGIA
PAK CHOI

PARSNIP
Pea, Flat
Polar Grass
POTATO
Radish, Field
Reed Canarygrass
SAINFOIN
SPRUCE
ST AUGUSTINEGRASS
TEFF
TIMOTHY
TREFOIL
VETCH
WATERMELON
[forage grasses]
[some vegetables]
[tubers]
WHEAT
WHEATGRASS
SAFFLOWER
Salicornia
SESAME
Stevia
SUNFLOWER
ZOYSIA
[oil crops]
[amenity grasses]
[fibers]
Peach
PEPPER
PHACELIA
PHLOX
POPPY
PRIMROSE, CAPE
PUMPKIN/SQUASH/GOURD
RADISH, TABLE
Rutabaga
SNAPDRAGON
SPINACH
STEIRODISCUS
STOCKS
SWEETPEA
TRACHELIUM
TURNIP
VERBENA
VINCA
ZINNIA
[all ornamentals/flowers]
[some vegetables]

NOTE: Crops listed in all CAPS have an objective form (Exhibit C) finalized. This includes forms that will not be printed, but are considered final.

If you are preparing an application, you need to get an application form, an Exhibit E form, and an Exhibit C form (specific to your crop). We also have copies of the PVP Act and Regulations and Rules of Practice, and the Official Journal Index.

How to Contact Us:
USDA, AMS, Plant Variety Protection
NAL Building, Room 400
10301 Baltimore Avenue
Beltsville, MD 20705-2351, USA

Main Office Phone: 301–504–5518 (8:00 am to 4:30 pm EST)
FAX: 301–504–5291
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Appendix 5.2. Plant Variety Protection Application Form (two pages).

6

Farmers' Rights Over Plant Genetic Resources in the South: Challenges and Opportunities

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Introduction

The pedigree of many modern varieties of major food crops can be traced to local varieties conserved by small and marginal farmers in high-risk environments. Until recently, these biological resources were recognized as the common heritage of humankind. Similarly, modern scientific institutions for crop improvement were also established on the same ethos of a common heritage to facilitate access, exchange and improvement of potential genetic material in different regions of the world (Brush, 1996). Although this approach has delivered a significant amount of public goods, it has come under scrutiny with the advancement of collaboration between public and private sector research institutions, especially with the advancement of biotechnological tools. These new biotechnological tools, as well as plant varieties developed by using them, are generally protected by strict proprietary rights that can prevent anyone from using them for research or commercial purposes without paying the appropriate royalties. These changes in the institutional and policy environment have led to the emergence of the issue of farmers' rights, which has spurred a polarized debate among various stakeholders. Though many issues and concerns raised in this debate have significance for both the South (i.e. undeveloped and developing countries) and the North (i.e. developed countries), this chapter analyses them in the context of the rights of small and marginal farmers who carry the burden of on-farm conservation of plant genetic resources in the economically poor, but gene-rich South.

 Intellectual Property Rights in Agricultural Biotechnology. Second Edition (eds F.H. Erbisch and K.M. Maredia)

Genesis, Concept and Scope

In a quest to counterbalance the stronger property rights recognized for formal breeders of commercial plant varieties, the Food and Agriculture Organization (FAO) commission on plant genetic resources formally introduced the concept of farmers' rights through a special resolution (5/89) annexed to the original FAO International Undertaking of 1983. The FAO resolution (FAO, 1989), unanimously signed by all its member countries, describes farmers' rights as:

> …[R]ights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in centers of origin/diversity. These rights are vested in the international community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions.

According to the FAO's resolution (5/89), farmers' rights are international in scope and need not be subject to national legislation. This is based on two principles: first, on an ethical consideration to ensure 'equity' in accessing plant genetic resources for food and agriculture (PGRFA); secondly, on a utilitarian logic for stemming the erosion of PGRFA. On the other hand, proponents of farmers' rights have raised the following four major issues over time: (i) the right to grow, improve and market local varieties and their products; (ii) the right to access improved plant varieties and use farm-saved seeds of commercial varieties for planting and exchange; (iii) the right to be compensated for the use of local varieties in the development of new commercial products by outsiders; and (iv) the right to participate in decision making processes related to acquisition, improvement and use of PGRFA.

Farmers' Rights and International Agreements

Although the issue of farmers' rights has remained at the centre of international debate in many political, academic and scientific fora, hardly any attempt has been made to define these rights in legal terms (Bragdon and Downes, 1998). There are several international agreements and conventions on trade, agriculture, environment and human rights that affect the operationalization of different elements of farmers' rights. Many of these agreements and conventions are still evolving, if not stalled, under polarized debates between the North and South. Some major provisions and implications of these agreements and conventions are briefly discussed here to give an overview of the complexity involved in effective implementation of farmers' rights in developing countries.

International Treaty on Plant Genetic Resources for Food and Agriculture

The increased recognition of the interdependence of most countries with respect to their requirements for PGRFA encouraged all the member countries of the FAO to sign a non-binding international agreement in 1983, known as the FAO International Undertaking of 1983. As mentioned earlier, farmers' rights were recognized through a separate FAO resolution (number 5/89) attached to this FAO International Undertaking in 1989. The FAO International Undertaking proposed to operationalize farmers' rights by 'establishing a mandatory international fund to support conservation and utilization of PGRFA through various programmes particularly, but not exclusively, in the Third World' (The Keystone Center, 1990: 25). The Keystone International Dialogue series, an informal forum for consensus building among various FAO members on policy issues related to PGRFA, strongly recommended general compensation for farmers, but not specific to any individual, community or country. Many academic scholars, scientists and activists, who considered farmers' rights as 'collective rights', acclaimed the FAO International Undertaking even though it legitimized free access under the umbrella of 'interdependence'. The proposed international fund in support of farmers' rights was never effectively operationalized and ultimately has come to a *de-facto* end. As an alternative, FAO members decided to operationalize farmers' rights through the Global Plan of Action (GPA) adopted at the Leipzig conference held in 1996. As with many other outstanding plans, however, the highly applauded GPA has suffered a lack of sufficient funding and thus has become just one more document on file supporting farmers' rights.

In 1994, the FAO initiated an intergovernmental negotiating process to revise the International Undertaking of 1983 and to make it a legally binding agreement, harmonized with the provisions of the Convention on Biological Diversity (CBD). After a decade-long discussion on the scope and implications of the revised international agreement, 113 member countries of FAO agreed to sign a new agreement on 3 November 2001: the International Treaty on Plant Genetic Resources for Food and Agriculture. Article 9 of the International Treaty reaffirms its commitment to farmers' rights as: (i) protection of traditional knowledge relevant to PGRFA; (ii) the right to equitably participate in benefit-sharing; and (iii) the right to participate in decision making at national levels on matters related to conservation and sustainable use of PGRFA. Ironically, the most important issue of farmers' rights – to use, exchange and sell farm-saved seeds of local as well as improved varieties – has been left to the sole discretion of national governments. The International Treaty aims to achieve farmers' rights through an exchange of information, facilitating access to and transfer of technology, capacity building and sharing of monetary and other benefits of commercialization. The most significant change included in the new International Treaty is perhaps its provision on intellectual property rights (IPR) relating to PGRFA accessed through a proposed multilateral system

(articles 10, 11, 12 and 13). According to article 12.3(d), a recipient of any germplasm through the multilateral system shall not claim any intellectual property or other rights that limit access to plant genetic resources 'in the form received from the multilateral system'. This implies that germplasm, in its original form as received from the multilateral system, cannot be protected; but any genes, advanced lines or cells, DNA sequences, chemical compounds, etc. derived through value-addition research from this original material can be protected. Many civil society groups strongly appealed to remove the phrase 'in the form received' from article 12.3(d) as it grossly undermines the provisions of farmers' rights (ITDG, 2001).

Although the new International Treaty appears to be more comprehensive in its treatment of farmers' rights in comparison with the original resolution (5/89), it does not offer any additional support to ensure the effective implementation of these rights. The most significant problem with the International Treaty is that it does not recognize the rights of individual farmer-breeders who often develop new plant varieties through systematic efforts similar to those of institutional plant breeders using scientific approaches. Another limitation of the treaty is that it includes only a limited number of species of major food and forage crops, leaving many species that are crucial for the livelihood of farming communities in the South out of its purview.

Convention on Biological Diversity

The Convention recommends using biological resources sustainably and equitably sharing any benefits arising from the use of genetic resources. Provisions made under article 15.5 of the CBD requiring prior informed consent of the party owning the natural resource brought an end to the free or common heritage approach used for accessing PGRFA from farmers' fields. Article 8(J) of the CBD promotes a wider application of knowledge, practice and innovations relevant to sustainable use and conservation of biological diversity with the equitable sharing of benefits arising from its utilization. Although the revised International Treaty on PGRFA signed by FAO members claims to be in harmony with the CBD, it ironically ignores important provisions from the CBD regarding the requisition of prior informed consent.

The International Union for the Protection of New Varieties of Plants (UPOV)

Under UPOV-1978, farmers' local varieties remain as 'open access' because they rarely meet requirements of 'uniformity' and 'stability'. UPOV-1978 has a universal provision entitled 'farmers' exemption',

which allows any farmer who buys seeds of a protected variety to save seeds from resulting crops for subsequent replanting without having to pay additional royalties to the original plant breeder. The seed industry has consistently lobbied various governments to limit farmers' exemptions, as well as researchers' exemptions, provided under UPOV-1978. Their efforts were realized when the UPOV-1978 was revised in 1991.

The major changes made in UPOV-1991 that affect farmers' rights are as follows.

1. The provision of farmers' exemption is now optional (article 15.2) instead of mandatory. It is now the decision of each member nation whether to provide the farmers' exemption or not, and to what extent.
2. Plant breeders' exemptions (articles 14 and 15.1) are limited. Essentially derived varieties cannot be marketed without permission from the original plant breeder. This increases the monopoly of large companies and indirectly affects farmers' choice in the market.
3. Under UPOV-1978, member countries are not allowed to grant utility patents for sexually reproduced plants, while UPOV-1991 (article 35(2)) is not clear in this regard. The revised UPOV-1991 has received independent status from UPOV-1978 because many developing countries resisted changes made to the original agreement, demanding a continuation of UPOV-1978.

Trade-related Aspects of Intellectual Property Rights (TRIPS)

Until the announcement of the landmark decision by a US Court on the Ex-Parte Hibberd *et al.* case in 1985, agreements like TRIPS on safeguarding industrial IPR did not have significant relevance to farmers' rights. In the context of farmers' rights, the most important clause of TRIPS is article 27.3(b) under which 'WTO members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof' (Bragdon and Downes, 1998: 10). The exemptions provided for farmers, as well as plant breeders, to use varieties protected under the Plant Varieties Protection Act have ceased to exist under the Utility Patent Act (TRIPS).

There is considerable misunderstanding surrounding the application of TRIPS to local varieties existing in farmers' fields. Many activists claim that any local varieties could be patented directly under the Utility Patent Act, and thus could ultimately prevent farmers from using them. Since developing countries have been granted a 10-year period ending in 2005 to ratify TRIPS, they are still in the process of interpreting the meanings of various provisions in the best interests of their own countries. For instance, the provisions of exception under article 27.2 on *Ordre Public Morality* and article 27.3(a) on exclusion of diagnostic, therapeutic and

surgical methods for humans, animals and plants from patentability can be positively exploited for protecting the interests of small and marginal farmers. Many scholars have also discussed the application of geographical indications available under TRIPS for protecting farmers' rights over their local varieties that have a strong association with a particular ecosystem and culture – and have a unique appeal in the minds of consumers (Gupta, 1999; Juma, 1999; Correa, 2000). For instance, the *Basmati* variety of rice grown in India and Pakistan could qualify for protection under the category of geographic indication.

The UN Commission on Human Rights and International Labour Organization Conventions

Posey (1994) has discussed various provisions of the 1948 Universal Declaration of Human Rights (UDHR) that can be positively exploited to protect local people's rights over their genetic resources and cultural properties under the framework of basic human rights. The working group of the United Nations Economic and Social Council (ECOSOC) on Indigenous Populations submitted a report in 1993 tentatively referred to as the 'Draft UN Declaration on the Rights of Indigenous Peoples'. Article 29 of the Draft UN Declaration has a provision to take special measures to control, develop and protect their human and other genetic resources including seeds and knowledge of the properties of fauna and flora (Bragdon and Downes, 1998: 25). Similarly, provisions made under article 7 on the 'right to decide [their] own development priorities' (Posey, 1994) and article 4 on special measures 'to safeguard institutions, property, labour, culture and environment of the indigenous people' (Bragdon and Downes, 1998) under the International Labour Organization (ILO) Convention 169 can be employed for protecting the interest of farmers' rights in the South. In addition to the ILO Conventions and the Draft UN Declaration, the UN Human Rights Commission and the FAO jointly submitted a report in June 1999, which suggested that farmers' rights should be pursued as a 'right to food' (Crucible Group II, 2000: 58).

Farmers Rights and Stronger IPR Regimes: Concerns and Critiques

The application of current IPR regimes on plant genetic resources is considered an extension of various notions held by the industrial world to local communities dependent on natural resources, whose rights are recognized by non-market mechanisms. Brush (1994) argues that as the value of genetic resources and associated knowledge systems increases

under the proposed proprietary regimes, the pressure to claim them as 'exclusive property' may increase. Logically, such an outcome may result in conflicts within communities, which may adversely affect the socio-cultural practices of seed exchanges that have been so crucial for the maintenance and evolution of farmers' varieties. Although existing genetic diversity of local varieties is an outcome of cumulative efforts for more than 5000 years, there are very few empirical case studies (Gupta, 1993, 1999; Soleri *et al.*, 1994) that elaborate an understanding of local communities towards any concept of property rights related to local varieties. A lack of thorough documentation detailing the history of farmer-breeding may be a major reason for the failure to consider the possibility that farmers have any inherent intellectual investment or property rights over their particular local varieties (Cleveland and Murray, 1997). In the absence of rigorous empirical studies on traditional concepts of property rights over local varieties, it is extremely difficult to construe farmers' rights in a form that is compatible with the value system of farming communities in the South and that can be operationalized within the current institutional environment of mixed communities influenced by a shared market economy.

The current debate on farmers' rights has created the notion that local varieties and associated knowledge systems in the South are 'traditional' – an outcome of 'collective' efforts of local communities made several centuries ago – and have always been maintained in a fossilized form under the 'open access' regime. Gupta (1993, 1999) questioned some of these universally applied assumptions made in the context of property rights over plant genetic resources and highlighted several examples of contemporary farmer-breeders documented by the Honey Bee Network in India (Gupta, 1999). These farmer-breeders have unique knowledge and sets of practices and skills, which are not known to every person in their community. Many of these farmers accept special material compensation, usually higher prices, from the farmers who purchase seeds from them. They also ascertain their rights by naming such varieties with their family or village name. If the entire genetic pool of farmers' varieties is to be considered as traditional, collective and common heritage and subsequently treated uniformly under the IPR regime, it may undermine the contribution of contemporary individual farmer-breeders.

There is growing concern that a stronger IPR regime may lead to the skewing of research towards only a few commercially important crops perhaps grown predominantly by farmers in well-endowed regions. The expansion of powerful foreign as well as domestic private sector firms, aided by biotechnological tools, may legally prohibit farmers from using or exchanging farm-saved seeds of protected varieties without paying appropriate royalties. However, it is most likely that developing countries would legislate their national policies to ensure farmers' rights for

using and exchanging their own farm-saved seeds of protected varieties. In such circumstances, the private sector may intensify its bias towards developing seeds using the technique of hybridization or inserting terminator genes, as these technologies have built-in protection systems against brown-bag selling or re-use of farm-saved seeds by farmers. There is no doubt that these technologies would have high environmental risks and negative socio-economic externalities on small and marginal farmers. The expansion of the private sector in developing countries may also intensify the replacement of diverse gene-pools in farmers' fields with improved plant varieties characterized by 'stability' and 'uniformity'. The loss of diverse gene pools containing high intraspecies variability would severely affect the sustainability of agriculture in high-risk environments.

Another concern raised against stronger IPR regimes over PGRFA is the increasing trend towards consolidation and mergers among large seed, agrochemical and pharmaceutical manufacturing companies resulting into monopolistic markets. Beyond its adverse economic impact, the strategic linkage between seed and agrochemical industries could prove to be a serious threat to local genetic diversity and food security. Seeds function in a similar manner to 'an operating system' of a computer. Once such an 'operating system', which requires a particular environment (fertilizer, herbicide, pesticide, etc.) is in place, and its alternatives are wiped out through monopoly or through the overwhelming success of a particular variety, there is hardly anything left under the control of farmers.

In addition to strong protests, especially against the entry of transnational seed companies in the South, there are a number of court cases challenging patents on new varieties developed by the private sector in developed countries. Simultaneously, the private sector has also filed cases challenging farmers' practice of brown-bag selling or other use of their varieties without legal permission. With few exceptions, US courts have always safeguarded the interest of industry and prevented the 'infringing of patents' with exorbitant penalties. Even if courts in developed countries show their sympathy towards small farmers in the South, a question arises: who will have sufficient resources in the economically poor South to hire the expensive services of a patent attorney for protecting his/her interests in such legal matters?

The advocates of IPR argue that, in the absence of property rights over plant genetic resources, there would be no incentive to conserve biodiversity for either nation-states or communities other than for altruistic reasons. One of the most convincing arguments offered in support of recognizing property rights is that it will serve as an instrument to raise much of the needed scarce resources for conservation in the gene-rich South (Gupta, 1999; WIPO, 2001). Whether these additional resources will reach farmers and then translate into action for on-farm conservation of local agrobiodiversity is difficult to predict.

Challenges and Opportunities

Genes flow across space, time and sociocultural systems. Furthermore, they are characterized by subtractive as well as non-subtractive resource use patterns. Due to these inherent characteristics of plant genetic resources, it is extremely difficult, if not impossible, to assign any property rights over them. The complexity and confusion concerning farmers' rights increases due to lack of clear understanding on which international agreement prevails over another and under what circumstances. The hegemonic potential of some of the international agreements and the quest for protecting national sovereignty have created challenges for the evolution of an effective system of governance at an international level for operationalizing farmers' rights over plant genetic resources. For instance, many developing nations are demanding that the superior status of CBD be recognized, which essentially implies that every patent application based on genetic material or an associated local knowledge system has to ensure that the patentee has acquired the genetic material legally and with the prior informed consent of the original owner of that particular material. On the other hand, industrialized nations have not only demanded that TRIPS takes priority, but have also sought review of article 27.3, which provides some leverage on the patenting of plants and other living organisms, except microorganisms. Similarly, indigenous communities have asked for not only the superior status of the Draft UN Declaration on Human Rights to be recognized, but also many other agreements and charters independently developed by them.

Correa (2000) recommended the following amendments in the existing system of IPR in order to protect certain components of farmers' rights: (i) the application of geographic indications and copyright for protecting local varieties and associated local knowledge systems; (ii) increasing the flexibility of the requirements such as 'uniformity' to help in protecting farmers' varieties; (iii) introducing new requirements in the patent application to declare the origin of genetic materials used in the invention. In a similarly optimistic view about IPR reforms, Gupta (2000) noted some of the indicators of positive change among the major players in the field of IPR. He referred to an official request from the US Patent and Trademark Office (US PTO) seeking the help of the Council for Scientific and Industrial Research (CSIR) – a research institution funded by the Government of India – for documenting traditional knowledge and making it available in electronic form so that it can be identified as 'prior art' by US PTO. Though US patent laws do not recognize oral knowledge outside of their geopolitical boundaries as 'prior art', this has been a positive move towards avoiding unfair and trivial patents, which often infringe on farmers' rights. Crucible Group II (2000: 85) proposed appointing an ombudsman under the World Intellectual Property Organization (WIPO) and UPOV with the power and resources to institute an official inquiry against any claim of property rights that may infringe upon the rights of local communities.

Some civil society groups have insisted that the FAO should forward the issue of farmers' rights to the UN office of the High Commissioner for Human Rights in order to consider it in the framework of 'right to food' (ETC Group, 2001). Coombe (1998) explained the scope, complexity and consequences of operationalizing IPR over plant genetic resources under the hierarchical framework of international human rights. She argues that nation-state signatories to various international human rights conventions do retain a significant power, though largely untapped, to ensure that IPR serve larger goals of global social justice. However, Gupta (1999) suggested that simply considering the issue of farmers' rights under the current concept of human rights influenced by Western societies may not serve the purpose of local communities. He notes that the Western definition of human rights still does not legally recognize the act of taking something, without due compensation, from someone who is not aware of its full worth to be construed as fraud. Thus, not only the principle of informed consent but also the investment in creating the capacity of farming communities for such consent has to be considered. Hence, the new IPR regimes must consider the compulsory requirement of 'lawful' and 'rightful'[1] acquisitions of genetic material from original sources.

Conclusion

Most of the international agreements discussed are still under negotiation or in the process of being ratified and implemented by nation-states. The realization of farmers' rights would depend on how nation-states in the South legislate their national policies for accessing genetic resources and protecting innovations based on knowledge systems associated with genetic resources. These new policy instruments should provide incentives to individual farmers as well as communities to conserve, grow and improve the diverse gene pool. A new policy environment should also have minimum negative impact on the flow of genetic material for research. In turn, public institutions have to deliver new technologies in competition with the private sector and ensure that these technologies meet the interests of small and marginal farmers in high-risk environments. Finally, non-governmental organizations and activists should make efforts towards the capacity building of local communities so that they can negotiate directly with policy makers and potential external users of local PGRFA and ensure that requirements of prior informed consent and benefit sharing are met.

[1] The doctrine of 'rightful' acquisitions demands pursuit of the best ethical behaviour possible rather than merely legally correct behaviour. In the absence of appropriate legal mechanisms for accessing genetic resources in many developing countries, external users should ensure 'rightful' behaviour instead of taking advantage of a weak legal regime (Gupta, 1999).

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7

Economic Aspects of Intellectual Property Rights in Agricultural Biotechnology

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Introduction

In an era of growing land and water scarcity, the creation of scientific knowledge and its application through new technologies, such as biotechnology, increasingly underpins sustainable agricultural growth. Various forms of intellectual property (IP) (e.g. patents, copyright, plant breeders' rights, trademarks and several other types of intellectual property rights or IPR) have been developed and, over the years, refined and strengthened to provide incentives for knowledge creation, especially in the private sector. Reflecting society's objective of balancing the interests of producers and users of new knowledge, IPR differ in terms of the products that may be eligible for protection and the scope and duration of protection.

There are two major economic themes associated with the application of IPR to agricultural biotechnology. The first is the trade-off inherent in all IPR schemes between providing sufficient monopoly powers to the innovator (e.g. private firm or individual) to ensure economic incentives to invest in research and development (R&D) versus giving wide and inexpensive access to the innovation, once developed. The second theme relates to the influence of biotechnology and IPR on the role and mission of the public sector in agricultural research. In other words, should public research organizations provide open access to their

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research results, or should they also protect their IP? How can public research organizations access proprietary tools needed for their research programmes. In this chapter, we set forth the economic principles for analysing each of these themes, present empirical evidence on the consequences of IPR and discuss the economic and policy issues most relevant to biotechnology in developing countries.

National Dimensions: How Strong Should Intellectual Property Rights Laws Be?

The trade-off between profit and access

The main output of investment in R&D is the creation of knowledge, sometimes embodied in new inputs (e.g. seeds) and sometimes as 'stand-alone' knowledge products (e.g. new management practices such as recommendations for integrated pest management). In a static setting, the greatest level of social benefits occurs with the widest possible dissemination of new knowledge. But if everybody can freely access new knowledge, inventors have little incentive to commit resources to producing it. IPR temporarily transform knowledge from something that is available to all (a public good) into something that the inventor can choose to sell to a restricted audience (a private good). Recognizing that successful invention usually requires investment of time, effort and money, IPR protect ownership of the fruits of these investments. Creative minds and innovative firms thus have an incentive to engage in inventive activities, thus leading to faster technological progress.

The trade-off issue arises because of the way in which IPR allow inventors to recover their investments – for example, let us think of seeds for a transgenic variety. IPR (in this case, patents, plant variety protection (PVP) or a trade secret) allow the owner of a new invention (the transgenic variety) to charge a premium over what competitors (without access to the invention) can charge for their seeds and over what it costs to reproduce the seeds. It is this premium that provides the motivation to invest resources in the inventive activity. However, the new seeds can be cheaply reproduced, and without the enforcement of the IPR that allow the price premium, they would be more widely and more rapidly diffused, with consequent higher benefits to society at large. This leads to a paradoxical situation. The availability of profits motivates the invention in the first place, so without these profits the invention would not be available at all. Yet generating such profits through a price premium restricts usage and may lower the overall benefits to society.

The trade-off between allowing profits to stimulate further innovation and opening access to the innovation is a sticky issue. Drugs to combat HIV/AIDS provide a good example. These drugs were developed

through heavy investment by the pharmaceutical industry and placed on the market at a cost of annual treatment per patient of over US$10,000. However, the actual cost of manufacturing and distributing the drugs is only about US$200 per patient. For the majority of HIV/AIDS sufferers, who are poor, the market price of the drugs was way above their ability to pay, until international lobbying persuaded the companies to lower their prices in developing countries and to allow developing countries to import generic versions of the drugs.

A second issue is whether the protection of an invention will help or hinder the pace of further R&D. This is especially so for biotechnology where one scientist's innovation may be dependent upon patents held by others. The inventor of a new transgenic variety may have to deal with at least the following types of prior IPR: (i) protected varieties into which the genetic material is to be inserted; (ii) patented gene insertion techniques; (iii) patented gene promoters; (iv) patented marker sequences; and (v) previously incorporated patented traits (and their underlying genetic sequences). For example, transgenic plant varieties may contain multiple transgenic sequences, each 'created' and patented by a different inventor. The 'Golden Rice' variety is protected by over 40 US patents, although much fewer in developing countries (Kryder *et al.*, 2000); Pioneer brand 37R71 YieldGard® insect-resistant maize is labelled as 'produced and licensed under one or more' of 154 US patents (many of which have little to do with transgenics).

Other types of biotechnology inventions may have similar problems with previously held patents. For example, it is still an open issue as to how many genomic and proteomic sequences will be available in the public domain, and how many will be patented and available only for a fee. The issue is whether reliance on previously patented research processes and products facilitates further innovation (patenting requires disclosure of the invention) or whether it hinders further innovation (inability to commercialize new innovations that rely on prior patents without permission of the patent holder). It has been argued that having genomic information fully in the public domain would provide a tremendous boost to inventive activity in both the public and private sectors, and some scientists have proposed ways that this might be negotiated (Fischer *et al.*, 2000; Nuffield Foundation on Bioethics, 2002).

Intellectual property rights and technology transfer

There is little empirical evidence of the impact of patents and plant variety protection certificates (PVPs) on the rate of technology transfer or on the stimulation of local research in developing countries (Seibeck *et al.*, 1990; van Wijk *et al.*, 1993). The effects of patents on technology transfer are disputed. One view is that they assist the technology transfer process

in two ways: (i) the published patent discloses information to the benefit of other researchers; and (ii) the ability to retain control over their technologies allows companies to transfer complementary skills to other countries – either through licensing agreements or through foreign direct investment (Braga, 1995; Henderson *et al.*, 1996). According to this viewpoint, IPR can assist in the diffusion process of new knowledge within and between economies.

PVPs can assist transfer of varietal technology by stimulating foreign breeders to make available their varieties and germplasm. For example, after New Zealand adopted PVPs in 1973, over 60% of the applications for protection by 1990 were for foreign-bred varieties. It is significant that this was not the case for growers in Australia where PVP protection was not available at that time. Likewise, it is generally believed that PVPs have allowed Chile to gain access to the latest fruit technology from California. However, it is important to note that foreign investment in developing country seed markets depends on many factors beyond IPR, especially general economic policy and market size (Pray and Umali-Deininger, 1998).

Another view, however, is that strong IPR may restrict the free flow of new knowledge and scientific information and thus inhibit scientific creativity and technological change that traditionally occurred through imitation (Helpman, 1993). In developing countries, the absence of patents enables their infant industries to examine and copy products and develop local production capacities – as occurred in the now-developed countries in the 19th century. Although investment in local R&D may be negatively affected, this may be more than compensated for by the inflow of new technologies. Theoretically it is far from clear that all countries should be required to maintain the same level of IPR (Trebilcock and Howse, 1999). Many economists argue that the experience of economic history is that copying to catch up is the only way to catch up. In agriculture, a large share of scientific knowledge used in developing countries (especially the poorest ones) is in the public domain and not covered by IPR (Braga *et al.*, 1998). The World Bank suggests that strong IPR can disadvantage developing countries by increasing the knowledge gap and by shifting bargaining power towards the producers of knowledge, most of whom reside in industrialized countries (World Bank, 1999).

Intellectual property rights and investment in research and development

In theory, stronger IPR should encourage more research and development in countries where they exist. Nowhere is this more apparent than in the USA in the biotechnology arena. The biotechnology industry barely existed prior to the landmark Supreme Court decision of Diamond v. Chakrabarty in 1980, where the court held that anything

made by the hand of man was eligible for patenting. Since that decision, the biotechnology industry in the USA has flourished and now comprises over 1200 biotechnology companies. Likewise, supporters of the Bayh–Dole Act in the USA point to the effect of extending IPR to public sector research on increasing licensing income and the number of start-up companies spinning off from universities. In 2000 it was estimated that the gross royalty income for universities in the USA amounted to US$678 million, and that over 3000 start-up companies had been formed since 1980 (AUTM, 2002).

But there is 'limited empirical evidence' even in industrial countries that PVP leads to increased investment in R&D. An assessment by Butler (1996) found that the PVP Act (PVPA) in the USA stimulated the development of new varieties of two major self-pollinating field crops – soybean and wheat – but neither the costs nor the benefits of the PVPA were particularly striking. More recent analysis by Alston and Venner (1998) concluded that the PVPA in the USA has contributed to increased investment by state agricultural experiment stations in developing new wheat varieties, but there was no evidence that the private sector had increased its investment.

Given the short history of PVPs in developing countries, there is little empirical evidence on their impact. In Argentina, one of the first developing countries to implement PVPs, their enactment did not stimulate additional research expenditure but may have prevented a reduction in research expenditures in soybean and wheat (Jaffe and van Wijk, 1995).

It is difficult to generalize from these studies and it is likely that the effects of PVPs are quite crop and country specific. Foster and Perrin (1991) found that the number of PVP certificates increased: (i) with the value of the crop; (ii) with decreasing cost of enforcement; (iii) for crops with greater concentrations of producers; and (iv) for horticultural crops.

Several factors often prevent IPR from stimulating R&D investment in developing countries. These include problems of IPR enforcement in small-scale agriculture, the dominance of public research, which may undermine private incentives, lack of conducive economic policies for private investment, small market size, and trade restrictions on import and export of seeds. Given the lack of reliable empirical evidence, predictions about the likely economic effects of stronger IPR on research investment in developing countries have yet to be substantiated.

Economic and policy choices in the design of intellectual property rights systems

Countries must decide on the appropriate level of IPR protection to be provided through patents and plant variety rights (PVR). In general, countries with strong R&D capacity and a developing private R&D sec-

tor will want to provide stronger IPR protection to promote local R&D than poorer countries with weak R&D capacity, who depend largely on 'borrowing' technology from abroad (CIPR, 2002).

Developing countries who are members of the World Trade Organization (WTO) are obliged to establish an IPR system for agricultural biotechnology processes and products. To address the challenges of developing an IP system will require a careful analysis of the costs (including opportunity costs) and benefits to society of expanding IPR. This is a complex decision, since benefits are likely to be quite specific to agricultural subsectors. For example, access to new technologies and unimpeded exports by enforcement of IPR may be especially important in subsectors that depend on exports to Organization for Economic Co-operation and Development (OECD) countries, such as cut-flower production in Colombia and Kenya.

In addition, IPR laws without implementation are of little value, and implementing the IPR system involves a number of administrative and institutional costs to society (Table 7.1.). These include the costs involved in developing the appropriate laws and enforcement mechanisms. Patent examiners need special training to deal with biotechnological applications, and new examiners with degrees in biology and biotechnology will be required. For PVP, an appropriate administrative system must be established. Empirical evidence suggests that these direct costs to society could be particularly large in a developing country (Table 7.1).

However, these administrative costs may only be partially borne by governments. Patent and PVP offices can be self-financing operations through application and renewal fees. Administrative costs may be reduced by contracting some activities to universities and other institutions. However, a careful balance has to be struck between generating revenues for the administrative office and keeping fees sufficiently low to allow small-scale firms and public organizations to use the IPR system.

There are several other options for reducing costs. One option is to provide for a 'deferred system' (which exists in many countries), whereby a special request for examination needs to be made by the applicant within a given period (UNCTAD, 1996). The rationale for this system is that some inventors may decide to abandon the application, thus reducing the number of applications to be examined by the patent office. Another option for keeping costs down is to not require any patent examinations and let the patent holders defend their patents in court (e.g. in South Africa). Yet another option is to implement innovative, low-cost systems like petty patents, which can also ensure protection for a shorter time at lower cost (CIPR, 2002). Later, inventors can choose to seek a regular patent or let their petty patent expire. Finally, regional approaches to IPR can significantly reduce costs. For example,

Table 7.1. Costs to society of implementing stricter IPR policies: potential categories and empirical evidence.

Cost categories	Empirical evidence
DIRECT COSTS	
Drafting costs: drafting new laws and adjusting current laws	Evidence from developing countries suggests that these costs could be substantive. Some examples include:[a]
Establishment costs: national patent office, PVP office, new equipment, facilities	Chile: drafting and human resource development costs estimated at US$718,000, and annual and recurrent costs at US$837,000
Administrative costs: increased personnel to process and grant larger number of patent and PVP rights	Egypt: personnel and equipment costs estimated at US$598,000
Human resource development costs: training patent examiners, judges, PVP officers and administrative staff	Bangladesh: drafting costs to comply with TRIPS estimated at US$250,000, and annual operational, enforcement and administrative costs at US$1.1 million
Operating costs: computer facilities, searching national and international repositories, publication of bulletins, upgrading examination and registration systems	There is wide disparity in the requirements for implementing stricter IPR. The costs to a country will depend on specific circumstances of a country
Enforcement costs: judiciary framework, court system, litigation and infringement law enforcement, customs enforcement	
Other costs to society	
Increased prices of agricultural inputs	Limited evidence from developed and developing countries suggests higher prices (though not excessively high) [b]
	More studies are needed to confirm the price effects of IPR
Increased time and money costs in accessing research inputs by public research institutes	Lack of evidence on the issue of time and money costs

[a]Source: UNCTAD (1996). The costs are not specific to the implementation of agriculture-related IPR.
[b]Examples include: Lesser (1994) and Garcia (1998).

regional patent offices have been established in Africa that allow a single patent application to all member countries. Likewise, the European Union (EU) recognizes PVPs granted in any member country as applying in all other member countries.

Finally, to mitigate adverse impacts of the new international IPR standards, developing countries may also have to adopt or strengthen policies to reverse the potential adverse affects of IPR-induced monopolies. To minimize these social costs, governments will need to ensure competition from both the private and public sectors. The public sector may have to play an important role in continuing research in traditional crops and technologies and strengthening capacity in modern biotechnology research in order to provide options to farmers. Countries may also have to strengthen appropriate competition laws, use compulsory licensing, tighten the application of the traditional patent principles of novelty, non-obviousness and utility, and toughen application of the statutory research or experimental use exemption, so that patents cannot be used to bar research (Barton *et al.*, 1999; CIPR, 2002).

The Trade-off Between Generating 'Public Goods' and Encouraging Privatization of Knowledge

Intellectual property rights: a dilemma for public sector research

The traditional justification for public-sector involvement in agricultural research is that, even with the availability of IPR, the private sector cannot recoup its investments in many types of innovations and therefore will not invest in these areas. Such classic public goods include many agronomic and management practices and open-pollinated varieties. It makes less sense for the public sector to invest in those areas where IPR can be readily enforced (e.g. animal vaccines, hybrid varieties, agricultural chemicals and machinery). However, even for these types of inventions, investment by the private sector depends on many factors, including the ability to charge for an innovation. Thus, the public sector may have a relatively larger role to play in developing countries where the majority of farmers are small-scale farmers with limited purchasing power.

The mission of public research is thus to generate knowledge, technologies and products that promote the 'public good', that is, the best interests of society. Pursuing this mission demands that public research organizations practise 'open science', which means that scientists completely disclose all new discoveries to the scientific community (Argyres and Liebeskind, 1998). Full disclosure ensures the quality of research through peer review and replication, facilitates the development of future innovations and, hence, strengthens the mission of a public research organization.

However, the distinction between public goods and private goods is often blurred (van der Meer, 2002). A large share of biotechnology research takes place in the private sector and most tools and technologies are protected. However, the public sector needs access to these new tools

and technologies in order to comply with its mission. In addition, as funding of public research has been squeezed in recent years, many public research organizations have entered into commercialization agreements, not only to disseminate their products, but also to generate income. For these reasons, public research organizations may be able to justify protecting their inventions, both as a bargaining chip for negotiating access to tools in the private sector and as a means of entering public–private sector partnerships.

The increasing trend towards privatization of knowledge by seeking IP protection is challenging the definition of 'public domain'. Current patent systems offer no protection for indigenous and community-based innovation. The US patent on the Mexican enola bean, for example, raises the spectre of poor farmers being prevented from exporting beans that they have been breeding for centuries (Douthwaite and Ortiz, 2001). Lesser *et al*. (2000) contend that the trend towards privatization of knowledge is affecting the mission of public research in several ways:

- It discourages the practice of 'open science' since the opportunity to patent a discovery is lost when it is publicly revealed (based on the novelty criteria). A research contract with a private firm may also act as a limitation on the publication of results.
- It gives an institution control over the use of employee's innovations, including the right to grant exclusive licences.
- It restricts the ability of the researcher to further the commercialization process of a product that was developed using materials provided under a research material transfer agreement (MTA).
- The broadened scope of IPR in the area of plants and agriculture means that a scientist's research using patented tools could be infringing IPR and could lead to possible legal action.

These are all theoretical possibilities and can potentially impact the mission of a public research institute. However, in practice, a public institute has several options that gives it control over the outcomes of a publicly funded research programme. Even in the environment of an increasing trend towards protection, a public institute has the option not to protect the technology (unless it is required by the funding agency). If the decision is made to protect a technology, in practice, it still has control on the terms and conditions negotiated in an MTA or a licence agreement to mitigate the negative impacts of IP protection on the public sector mission.

Notwithstanding the concerns, there are many cases where it is economically and socially justified for a public research institute to protect its intellectual property (Maredia *et al*., 1999). This is especially the case when the protection of intellectual property helps to negotiate public–private cooperative relationships that speed the development and commercialization of new products and services based on publicly

funded research, but where the public sector does not have the business skills and 'venture capital' to bring the product to market. The IPR are needed to give protection to the private sector, in the form of an exclusive or non-exclusive licensing agreement.

Public institutions may also opt for protection for defensive reasons. In order to exhaust claims for protection by other parties, an invention has to be published completely, which is not always easy. Scientific publication may also be slow and possibly allow a third party to claim rights over the findings.

However, the institutional and technological shifts resulting from the increasing trend towards protecting intellectual properties mean that current innovations of public research programmes often rely on initial patents held by a number of different firms, or an initial patent held by a firm with strong market power. In the first case, the transaction costs of negotiating an agreement with all initial patent holders may be so high as to prevent commercialization. In the latter case, the initial patent holder has power to restrict or prevent commercialization or dissemination of products made with its technology. For example, transformation techniques, such as *Agrobacterium tumefaciens*, and the ballistic 'gene gun', which are employed for developing most transgenics, are patented and owned by private-sector firms, which may prevent the use of a variety developed using these patented tools, even when they have high social value (e.g. to alleviate vitamin deficiencies).

Economic and policy options for public research organizations

Policy makers in developing countries need to ensure that the R&D sector serves the agricultural sector well and safeguards the interests of farmers, by ensuring options (Fischer and Byerlee, 2002). With the changing 'rules of the game', IPR pose complex issues and challenges for public research institutes regarding both the use of IPR owned by others and protection of their own inventions.

Use of intellectual property owned by others

Most tools used in biotechnology research are protected, yet if the public sector is to fulfil its role, it must access many of these tools. Various options for accessing these tools are discussed in Byerlee and Fischer (2001) and summarized below with respect to the main economic aspects.

UNILATERAL ACCESS One option is for the public sector to unilaterally access a tool or technology, especially those technologies that can be easily copied, without seeking permission from the owner. This is perfectly legal in those countries where the particular patents have not been lodged,

provided that the product is not exported to a country where there is protection on the invention. Although this approach is limited by a number of factors, accessing the technology without IPR complications, if it is physically possible to do so, may sometimes be the most cost-effective approach, especially in small countries that are 'tool users'.

MATERIAL TRANSFER AGREEMENTS MTAs are now widely used to set conditions on the transfer of germplasm and research tools. In most cases, public research organizations have been using research tools and materials under an MTA for research purposes only, or with no formal agreement, leaving the need to develop a licence for commercial use of final technologies to a later stage. Although negotiation of use for the research phase only is much less complex, this practice can be detrimental to the use phase, since the greater the success of the research the greater the value of the technology and, therefore, the greater the expectation of returns by the owner when a licence is subsequently negotiated.

LICENSING AGREEMENTS Licensing in the form of an exclusive licence, a non-exclusive licence, or a cross licence has been widely used to transfer proprietary technologies. The first two usually require payment for the innovation, which requires a careful consideration of the benefits of the licensed product against the cost of licensing. The third is often associated with the use of IP as a 'bargaining chip' to gain access to useful proprietary technologies from others. Since the application of many products of biotechnology research requires incorporation into locally adapted germplasm, the public sector has the opportunity to use its own germplasm assets as a bargaining chip to obtain access to biotechnology tools and products, especially when serving emerging commercial markets of interest to the private sector.

In developing countries, the public sector may be able to negotiate a non-exclusive licence for use of the technology at no or low cost in certain markets – marginal areas, subsistence-oriented farmers and orphan crops – that are not of interest to the private sector. However, with the increasing presence of the private sector in developing countries, this segmentation of markets must be decided on a case-by-case basis and at the local level, since there are often major practical hurdles to overcome, especially the segmentation between subsistence-oriented and commercial farmers within countries.

PURCHASING INTELLECTUAL PROPERTY FOR RESEARCH AND USE Another approach is for the public sector to buy ownership of key proprietary technologies for use, again requiring a consideration of benefits versus costs. Cohen *et al*. (1999) reported over 50 instances where Latin American National Agricultural Research Systems have purchased proprietary biotechnology tools and products.

JOINT VENTURES Joint venture agreements are common for private–public collaboration in which each party contributes specific assets or knowledge and shares benefits according to an a priori agreement. In these arrangements, the public research organization usually provides the local germplasm and knowledge of its adaptation, and the private partner provides the new gene or genomic information. These arrangements are increasing rapidly in developing countries.

Protection of intellectual property rights

A further policy issue facing all public research managers is whether they should protect their own IP? Unlike in the private sector, where this decision is made based on expected future monetary benefits in relation to the costs of protection, in the public sector the critical question is whether in the absence of protection there will be a significant loss in the benefits to society as a whole from current or future innovations (i.e. whether the loss exceeds the cost of protection).

Technology transfer managers along with research administrators need to make decisions about whether or not to seek protection for a given technology and research product on a case-by-case basis. This requires policy guidelines on the following types of decisions (Barton *et al*. 1999): which inventions should be freely released to the public? Which inventions may be most efficiently brought to the user through the private sector and how can this be achieved in a transparent and equitable manner? Which inventions can be a potential source of income? Which inventions and assets can be used as 'bargaining chips' for cross-licensing? Which inventions need IP protection in order to keep them in the public domain?

Figure 7.1 lists some of these factors and speculates on how they may affect the IPR decisions of a public institute. Some are standard economic variables and are the same as those taken into consideration by a private firm. These include the cost and monetary benefits of protection, which are influenced by the potential rate of royalty payments expected from licensing the technology and the costs of seeking protection. The expected remuneration from licensing a technology will be influenced by factors such as the size of the market, competition and the capital investment needed to exploit the protected technology (Fig. 7.1).

Immediate direct costs to the research institute are the filing or application fees, attorney fees and the maintenance fee if protection is granted. This can be quite expensive if protection is sought globally. For example, the initial cost of a patent application in major European countries, the USA and Japan can be US$10,000–20,000 and more, depending on the legal and technical complexity involved (Blakeney *et al*., 1999). The estimated cost of seeking global patent protection may run in to hundreds of thousands of US dollars.

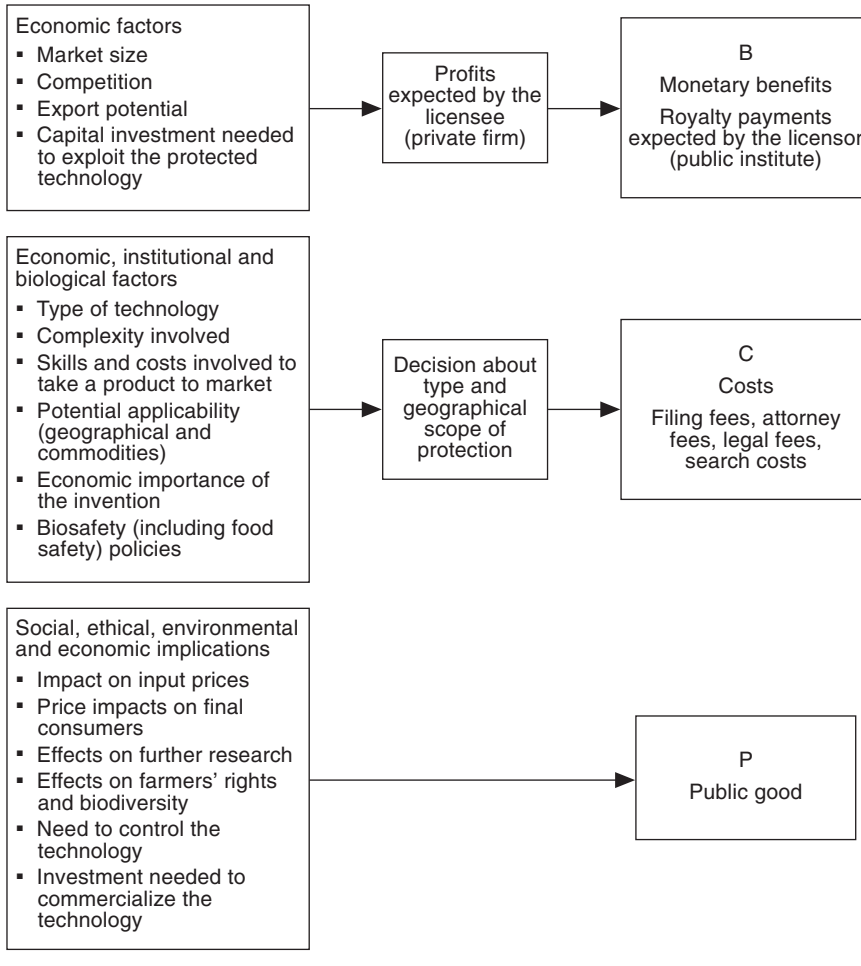

Fig. 7.1. Factors affecting the IP protection decisions of a public research institute: a decision framework

Even though monetary gains by themselves should not drive the decision of a public research institute to protect or not to protect a technology, they are none the less important and need to be considered in the decision-making process. Although the motive is not to reap monopoly profits, the public research institute has to consider whether the protected item will generate enough demand to attract private sector licensee(s) and make the protection costs worthwhile for the research institute (Blakeney *et al.*, 1999).

For a public research institute, there are additional variables that enter into the equation on both the cost and benefit sides. These include the implications of increased cost of inputs to producers of different

socio-economic groups, price implications for consumers, effects on the advancement of public knowledge, the impact on the accessibility of results for further research and the protection of farmers' rights (Fig. 7.1).

The decision to protect or not to protect a particular technology also depends on several economic, institutional and biological factors (Fig. 7.1). For example, in the case of plant varieties, a public institution may not have institutional capabilities to generate sufficient quantities of foundation seeds and make them available to seed companies to produce certified seed for commercial sale. In such cases, a public research institute will have to look for alternatives, which may require protecting the varieties and licensing them to other entities for seed multiplication. Institutional factors, such as biosafety and food safety policies, also play an important role in the decision-making process of seeking IP protection for a given technology.

In the framework of Fig. 7.1, the more the conditions favour the decision 'yes', the higher are the social and economic benefits of protection. The 'size' of the benefits and costs and the ultimate decision (yes or no) will, however, depend on the relative importance of each variable – monetary benefits, direct costs of protection, costs of bringing the product to market and the public good elements. Thus, even if the monetary costs and benefits are favourable towards 'yes' (i.e. B is greater than C), but the protected technology is perceived to impose limitations on a farmer's ability and rights to replant saved seed, which may be a very important objective of a public research programme, a research manager may decide not to protect a technology. In this case, the negative impact on the public good may far outweigh the monetary gains. On the other hand, even if the size of the market and other economic factors are unfavourable to justify protection (i.e. B is less than C), a public research programme may decide favourably if it perceives the need for a public institute to control who uses the innovation and wishes to use it as a bargaining chip for accessing the IP of others (i.e. P is positive).

The protection of a particular technology by a public research institute is thus a complex decision making process based on a broad economic and social assessment, often conducted informally, since many of the variables are difficult to quantify. As with many complex decisions, there is no easy solution, and the appropriate decisions will depend on the mission of the research organization, the IPR scheme in which it operates, the characteristics of the innovation and the socio-economic situation of its clients.

Conclusion

There are no easy generalizations about the potential benefits and costs of IPR regimes in developing (and even developed) countries, or about

the use of IPR by public research organizations. Instead there are trade-offs – IPR regimes and their use by public research organizations usually generate some benefits, but there are also associated costs. Whether the benefits typically, or in specific applications, outweigh the costs is an empirical question that often depends on the innovation, country, discovering institution, etc. For the poorest and smallest developing countries that largely depend on importation of new technologies, especially biotechnology, a limited IPR regime, such as a *sui generis* PVR system in accord with the Trade-related Aspects of Intellectual Property Rights may be most appropriate by providing maximum flexibility to import and use finished technologies. As local R&D capacity expands and the private sector share grows, a case can be made for stronger IPR protection. However, as this chapter has shown, there are significant costs in setting up and enforcing these regimes, although a number of more cost-effective options are available.

While the benefits and costs of IPR for individual countries will long be debated, they are a growing reality in most countries. Public research organizations must learn to operate in this new environment. They should continue to seek to maximize benefits to society at large by maintaining and delivering choices to farmers. The main policy issue is to ensure that public-sector research remains motivated by broader societal objectives and is not perceived as having 'sold out' to industry. Public sector institutes need to develop a clear and transparent policy that balances their role in providing public goods with the need to ensure sustainable funding, access proprietary tools and products and efficiently disseminate their products. This is often a difficult choice among: (i) ensuring that such commercialization is consistent with the public interest; (ii) applying intellectual property rights to protect technologies developed fully or partly with public funds; (iii) providing free access to protected technologies to other public research institutes; and (iv) sharing revenues between the central administration of a research institute, the department that undertook the work and the scientists generating the technology.

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8

Egypt

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Introduction

This chapter covers all Egyptian intellectual property rights (IPR) and their relationship to the General Agreement on Tariffs and Trade (GATT), with concentration on those rights dealing with Egypt's main economic recourse – agriculture. The chapter also discusses technology transfer contracts in relation to IPR.

National Perspective

Current status of intellectual property laws

Patents

Inspired by the Paris Convention for the protection of industrial property, which was passed on 20 March 1883, the Egyptian government issued a Law on Patents, Designs and Industrial Models (No. 132, 1949) and its modification by Law No. 47 of 1981. The main features of this law are the protection of new industrially exploitable inventions, new methods or processes of manufacture, and new applications of methods or processes already known.

The current law states that no patent shall be granted for inventions relating to substances prepared or produced by chemical processes and intended for food or medicine. One exception is when the substances are prepared or produced by special chemical processes or operations. In the

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case of operations, the patent shall only cover such methods or processes of manufacture and not the substance itself. The law also states that a register shall be held by the Academy of Scientific Research and Technology to record all inventions and particulars relating thereto.

The rights to an invention made by a worker or employee during working hours shall be vested in the employer. The term for a patent shall be 15 years from the date on which the application was made.

Some notable features of the law are discussed below:

- Section 2 of this law governs patent applications procedures. Should an application fulfil the conditions set forth in this section, the Patents Office at the Academy shall publish the invention as prescribed by the Executive Regulations. Any concerned person may object to the issue of the patent. The disposition is settled by a special judicial committee. One can contest the committee's decision before the Administration Court of the State Council. The patent is then issued by the appropriate minister.
- Section 3 deals with the assignment of the patent, its pledge and seizure.
- Section 4 deals with compulsory licences and expropriation of patents for public utility.
- Section 5 deals with the termination of a patent and its revocation.

The second chapter of the law is devoted to designs and industrial models. An explanatory memorandum affirms that food products are excluded from the law's domain. This is because food products are not classed as inventions, since they may pose risks to public health.

As from 1971, Presidential Resolution No. 2617 of 1971 vests the responsibility of patents in the Academy of Scientific Research and Technology, leaving, as before, the designs and industrial models to the Ministry of Supply and Internal Trade.

Copyrights (literary and artistic work)

Inspired by the Bern Convention of 9 September 1886, of which Egypt is a member, Egypt issued Law No. 354 of 1954 amended by Law No. 38 of 1992 and Law No. 29 of 1994 to protect original creation in the fields of literature and arts. The protection includes literary works, drawing and photographic works, musical works, geographic maps, audiovisual works and computer works or software. These provisions are in conformity with the Bern Convention, except the right for translation into Arabic.

Protection for literary work expires 50 years after the death of the author. For photographic works protection expires 15 years from the publication of the work, and for computer works or software, 20 years from the deposit of the original material. The law includes penalties for the violation of the provisions of the law.

Trademarks

Early in 1939 a law, No. 75 of 1939, concerning trademarks was issued. It was revised by Law No. 209 of 1956 in order to protect the names, signatures, words, numbers, drawings, symbols, addresses, stamps, profiles and any other features intended to differentiate them from any other products.

Such trademarks must be registered in the Commercial Registration Department, which has the right to approve the application or refuse it. The period of protection is 10 years and can be renewed.

This law also covers commercial data to protect the public from any false data about products in the market.

The last section of the law covers the sanctions for the violation of the law and the procedures for implementation.

Plant Variety Protection

In Egypt there are no plant variety protection laws. Some efforts have been made to adhere to the International Convention for the Protection of New Varieties of Plants held in Geneva on 23 October 1978, and its amendment on 19 March 1994. A draft law has been proposed for a new law to be attached to the draft law for the protection of all IPR in Egypt. This draft will be dealt with in the discussion of the draft IPR law.

Pending and Proposed Changes in Intellectual Property Rights

An effort has been made to gather the IPR elements in one code consisting of four books. The first book covers patents, utility models, integrated circuits and undisclosed information. The second book covers trademarks and geographic indications, and the third covers copyright matters. The fourth book is devoted to a new item, plant variety protection. The new material in each of these books will be covered in the following sections.

Patents

During the last decade, Law No. 132 of 1949 on Patents, Designs and Industrial Models has been subject to many proposed changes. While the first changes had been completed before Egypt joined the GATT talks, the last changes were completed only after GATT participation. Thus, before GATT, the law had been changed to encourage Egyptians to invent, to establish a scientific cadre and to introduce basic changes inspired from daily work and the public interest. The proposed changes were also intended to give employees, unless otherwise agreed upon, ownership rights in their inventions.

To make the law easier to implement, the utility model was also inserted (German Utility Model Law, 1968). This allowed a new tool's technical specifications to be included in the patent. The proposed changes created a link between the Patent Office and factories, introduced a full inspection of the patent and widened the competence of the judicial committee to have full authority over all conflicts arising out of the application of the law.

Another major change introduced food and pharmaceutical products as patentable subject matter and gave them full-term protection, as agreed under GATT. This reversed a trend and allowed a claim devoted to a non-naturally occurring composition, as in the US Supreme Court case: Commissioner of Patents and Trademarks v. Chakrabarty (case no.79–136, 16 June 1980) (Barton, 1991).

After Egypt had joined GATT and the World Trade Organization (WTO), and after the conclusion of the Uruguay Round's Trade-related Aspects of Intellectual Property Rights (TRIPS), many amendments were added to the draft. These amendments included:

1. Increasing the patent's term to the new international norm of 20 years from the application's filing date.
2. Removing provisions that allowed the government to expropriate patents for public utility and instead permitting only compulsory licences as outlined under TRIPS.
3. Asserting that the patent protection covers all fields of technology as outlined in Article 27 of TRIPS; the draft reads as follows:

(a) An invention patent shall be granted in accordance with the provisions of this law, for every new innovative step feasible for industrial exploitation whether in connection with new industrial products, new industrial ways or means or new applications of industrial known ways or methods.
(b) Here it is understood that the word 'industrial' means agricultural foodstuffs, medical drugs, pharmaceutical compounds, plant species, microbiological processes and their products.

4. Institution of the 'mail box' (Article 70/8), in which applications for patents not yet protected concerning pharmaceuticals and agricultural chemical products can be filed pending protection of these applications.
5. The grant of exclusive marketing rights (Article 70/9).
6. Protection of existing subject matter (Article 70/7).
7. The use without authorization of the right holder (Article 31).
8. Exhaustion (Article 6), which considers the owner of a patent to have exhausted his marketing rights in case he has already marketed his product in any other country.

The Egyptian Constitution (Article 151) also states that any international convention in which Egypt participates and ratifies is a law.

Presidential Resolution No. 72 of 1995, which made Egypt a WTO participant, was ratified by the House of Commons on 16 April 1995. The subsequent presidential ratification on 19 April 1995 made this Egyptian law.

A great debate ensued when deciding whether or not to delay for 10 years the implementation of the pharmaceuticals and food products provisions of TRIPS. The industrial pharmaceutical sectors argued for the delay, stating that it would allow them time to face worldwide competition (Reichman, 1993; Kabir, 1996). Other sectors, such as agriculture, trade and culture, argued for immediate implementation because they wanted to encourage investment (Federation of Egyptian Industries, 1996a,b). The House of Commons has been delayed in its final decision.

Plant variety protection

The plant variety reproduced in Egypt or abroad shall be entitled to plant variety protection subject to being registered in the register according to the law. The novel variety must be distinct, new, stable, uniform and have a name. The period of protection is 25 years for trees and vines and 20 years for other plant types.

The Minister of Agriculture has the right to give a compulsory licence without the consent of the breeder in the case of public interest and/or in case the breeder abstains from producing the variety. The breeder shall have the right of just condemnation. The last articles of the draft organize the penalties for the violation of the law.

Relationship between intellectual property rights and agriculture

Despite Law No. 132 of 1949 and its explanatory memorandum statements that the word 'industrial' includes the use of patents in agriculture, the memorandum excludes inventions of foodstuffs and pharmaceutical compounds since the law allows only 10 years' protection. Such an attitude, which covers genetic engineering, does not help promotion, development and investment, which Egypt greatly needs. Genetic engineering offers major tools for enhancing agricultural productivity and, hence, socio-economic development. Biotechnology research offers new tools and approaches to agricultural sustainability whereby food and fibre requirements may be met and the environmental quality enhanced. Egypt's failure to develop appropriate biotechnology applications and the inability to acquire technologies could deny timely access to new advances (M.A. Madkour, Cairo, 1996, personal communication).

The new draft law overcomes these provisions because it expressly states that it applies to agriculture, foodstuffs, plant species and microbiological processes and their products. Therefore, agriculture and its products are subject to protection as long as it is patentable subject matter.

Finally it is important to note that the House of Commons has agreed, after a long debate, to accept the new code consisting of four books. The new code, No. 82 of 2002, was issued in June 2002 stating that it shall come into force upon publication in the official gazette, except for those matters relating to substances prepared or produced by chemical processes and intended for food or medicine, which shall come into force in January 2005.

Technology Transfer, Commercialization and National Linkages to Third Parties

Licensing and other methods of technology transfer

Law No. 132 of 1949 is intended to organize the protection of patents and its procedures. The sole mention of licensing is made, as stated in the Paris Convention, only when the forfeit of patents and compulsory licences occurs. This prevents abuse that results from the exclusive rights conferred by a patent.

Decades ago, Egypt aimed at wide industrialization and adapted various plans for this target. Because the acquisition of foreign technology was important, Egypt began executing licensing agreements with the outside world. During the 1960s and up to 1974, we had no freedom to choose the technologies needed in, for example, scientific, technical and economic sectors. The main target was building factories, supplied with old technologies from Eastern European countries. It was rare to find a separate technology agreement. Most of the agreements included only a project study and report, engineering studies, supply of machinery and equipment, technical assistance, start-up tests, training and some legal terms. After the 1974 open-door policy, many agreements with Western countries were made. However, many difficulties arose. In particular, Western countries now had the opportunity to impose unfair terms and conditions; some of the terms and conditions included:

1. Demand for exorbitant licensing to be paid in a lump sum and/or running royalties for long periods of time.
2. Obligating the licensee to buy the machinery, equipment, spare parts and raw material from the licensor at high prices.
3. Limiting the right of licence to a specific project.
4. Rejecting the free exchange of any amendments between the two parties.
5. Limiting the right of the licensee to export the products to certain countries and/or at specific prices.
6. Imposing guarantee clauses not sufficient for the licensee.

During the 1970s, the UN General Assembly gave greater attention to technology transfer, and aimed to facilitate technology transfer to

developing countries. The UN Conference on Trade and Development (UNCTAD) conducted many sessions between developed and developing countries. In an effort to issue an international code of conduct, including fair terms of conditions for the transfer of technology to developing countries, Egypt participated in these sessions. However, no agreement was reached. The Academy of Scientific Research and Technology appointed a special committee to prepare a draft law for organizing the technology transfer contract. This draft law, which was inspired by the UNCTAD sessions and the Mexican law on licensing, has not been adopted. It is opposed by some sectors because they claim it restricts the open-door policy (El-Azab, 1995).

Egypt's General Organization for Industrialization is responsible for planning and encouraging industry projects, giving services and devices and working as a consultant. They also evaluate and prepare technology agreements. This helps Egyptian firms to sign agreements based on reasonable technical, financial, economic and legal conditions. These duties include: (i) informing the country about main technology sources; (ii) evaluating the draft contracts before signing; (iii) following up the technology supply phase; and (iv) helping to solve any problems that may arise between the two parties.

Other methods of technology transfer may arise by establishing collaborations with foreign firms' products. A new type of licensing in Egypt, called franchising, is also becoming available. A franchiser provides a standard package of products, systems and management services. Examples include McDonald's Restaurants, Kentucky Fried Chicken, Coca Cola and Pepsi Cola. In recent years, this kind of licensing has spread all over Egypt.

New commerce code

It is important to note that the new code, which was issued in June 2002 as No. 82 of 2002, includes a special chapter concerning the transfer of a new technology. This chapter takes into consideration the various precedents set earlier and challenges from the past.

Commercialization investment

In order to enhance development in Egypt, a special law was issued to encourage investment. Law No. 43 of 1974, amended by Law No. 230 of 1989, specifies that capital shall be deemed to mean seven items. These seven items include tangible assets such as patents and trademarks registered with member states of the International Convention for the

Protection of Industrial Property or in accordance with the rules of international registration contained in the international conventions. Through investment, IPR play a major role in development.

In reality, the adaptation of IPR in Egypt has encouraged investors to put capital into various projects. This idea applies to all kinds of investment in fields such as industry, agriculture and pharmaceuticals, all of which Egypt needs greatly.

Although the percentage of Egyptian patents issued to Egyptians, compared with those issued to foreigners, is only about 5%, Egypt feels that investment is urgent and that it needs to clear the way for investment by encouraging projects with more technology. In July 1996, the new government issued 24 new laws and regulations encouraging investment by reducing or abolishing taxes and fees, and shortening or abolishing the procedures or formalities for the invested projects.

Links to international organizations

By Law No. 165 of 1950, Egypt participates in the following international agreements:

1. Paris Convention for the Protection of Industrial Property (March 1883 and its amendments).
2. Madrid Convention for the Registration of Trade and Industrial Marks (April 1891 and its amendments).
3. The Hague Convention for International Deposit of Trade and Industrial Marks (November 1925 and its amendment).
4. Madrid Convention for Geographical Indications (April 1891 and its amendments).

Egypt participated in the Paris Union and in the Bureau for the Protection of Intellectual Property (BIRPI). Egypt also participates in the World Intellectual Property Organization (WIPO), which succeeded BIRPI. Using Article 4 of the agreement, WIPO gave assistance to Egypt by protecting its industrial property. Also, Egypt participates in the Food and Agriculture Organization (FAO) according to its rules.

Finally, another kind of cooperation exists between Egypt and the UN Industrial Development Organization (UNIDO). Egypt has been a member of UNIDO since its establishment. The purpose of UNIDO's Article 2 is to promote industrial development by encouraging the mobilization of national and international resources and to assist in promoting and accelerating the industrialization of developing countries. Particular emphasis is given to the manufacturing sector. The first Executive Director of UNIDO was an eminent Egyptian. At the outset of industrialization, Egypt received assistance from UNIDO through loans, technical assistance and training.

Illustration of an Intellectual Property Rights Application in Agriculture in Egypt

According to the patent records held at the Academy of Scientific Research and Technology, only one patent has been granted to Egyptian scientists in the field of agriculture, namely the patent granted to scientists from the Agricultural Genetic Engineering Research Institute (AGERI), Giza, Egypt. AGERI is a discipline-oriented research institute within the Agricultural Research Center of the Ministry of Agriculture and Land Reclamation. This patent is on a biological insecticidal gene, isolated from a bacterium (*Bacillus thuringiensis*) indigenous to Egypt. It is the first of its kind to be obtained in Egypt for biotechnology and molecular-biology-related products (M.A. Madkour, Cairo, 1996, personal communication).

Concerning biodiversity laws, Egypt participated in the Biodiversity Agreement concluded with UN Environment Programmes in Rio de Janeiro, Brazil, on 5 June 1992. With ratification on 6 May 1994, it became Egyptian law. No other laws have been issued.

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9

South Africa

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Introduction

The demise of apartheid heralded the start of a period of rapid change in South Africa, which is still in progress. While the transition to a democratic political system was remarkably smooth, socio-economic change has proved harder to achieve. Past government policy, aimed at marginalizing the majority of the country's citizens, created a conspicuous dichotomy within the country, in which first-world and third-world elements coexist. Many of the same conflicts waged between nations of the North and nations of the South in the global arena, around issues such as trade and agriculture, technology transfer, intellectual property rights (IPR), health equity, food security and biodiversity, are also experienced between different stakeholders within South Africa. The government is therefore faced with the task of formulating policy that, on the one hand promotes growth of the established economy and employment opportunities through exports and foreign direct investment, while on the other hand must improve the lives of the country's poorest citizens and eliminate the inequities that are a legacy of the apartheid regime. Striking the right balance is not always easy, as the necessary interventions are often seen to be competing, and available human and capital resources are severely limited. However, any policy interventions that do not take into account the different needs of the different sectors of South African society will not achieve the policy objectives. This is well illustrated by the technically complex and politically fraught topic of IPR.

The first section of this chapter provides an overview of key aspects of the current South African intellectual property (IP) regime and antici-

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pated future developments, with emphasis on areas of relevance to agricultural biotechnology. In the second section, the status of IP management is discussed and policy options are explored for strengthening the system. The third section assesses the impact of the national IP regulatory framework and existing IP management capacity on the development of agricultural biotechnology in South Africa.

Current Status of South African Intellectual Property Law

Overview

For a developing country, South Africa has a relatively strong IP framework in many respects, entrenched well before this became necessary for many other countries on acceding to the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). South African IP legislation has historically been based on British law and, more recently, European law, in particular the European Patent Convention (EPC). The main statutes of relevance and the government departments under which they fall are listed in Table 9.1, together with areas of envisaged legislation under discussion for some of the 'new' forms of IP.[1] Despite the South African Companies and Intellectual Property Registration Office (CIPRO) being a registration rather than an examining office, the system is considered to operate effectively for the most part, bolstered as it is by strong legislation upstream and enforced by competent courts downstream. However,

Table 9.1. South African IP legislation.

Type of IP	Statute	Department
Patents	Patents Act No. 57 of 1978	Trade & Industry
Copyright	Copyright Act No. 98 of 1978	Trade & Industry
Trademarks	Trade Marks Act No. 194 of 1993	Trade & Industry
Registered designs	Designs Act No. 195 of 1993	Trade & Industry
Plant breeders' rights	Plant Breeders' Rights Act No. 15 of 1976	Agriculture
Indigenous knowledge systems	Still to be enacted	Science & Technology
Farmers' rights	Still to be enacted	Agriculture
Biodiversity/access to genetic resources	Still to be enacted	Environmental Affairs & Tourism

[1] Additional IP legislation includes: Counterfeit Goods Act No. 37 of 1997, Merchandise Marks Act No. 17 of 1941, Performers' Protection Act No. 11 of 1967 and Registration of Copyright in Cinematograph Films Act No. 62 of 1977.

South African participation in the international patent system remains limited, as indicated by the paucity of patents issued to South African entities by foreign patent offices.[2]

Membership of international conventions

South Africa is a member of most of the international treaties and conventions governing IPR. Table 9.2 lists the main relevant agreements.

For the most part, South African IP law was TRIPS-compliant when TRIPS came into force. The Intellectual Property Laws Amendment Act[3] and the Counterfeit Goods Act served to amend the relevant IP legislation where remaining provisions did not meet TRIPS requirements.

South Africa is not a member of the African Regional Industrial Property Organisation (ARIPO), but has observer status. The levels of patenting activity in South Africa greatly exceed those in ARIPO member countries.

Intellectual property advisory committee

A Standing Advisory Committee on Intellectual Property, consisting of stakeholders from academia and the legal profession, was constituted to advise the Minister of Trade and Industry on IP policy matters. Sub-

Table 9.2. Membership of international treaties and conventions.

Agreement	Organization	Year of SA accession
International Convention for the Protection of Industrial Property (Paris Convention)	WIPO	1947
International Convention for the Protection of Literary & Artistic Works (Bern Convention)	WIPO	1928
Agreement Concerning the International Registration of Marks (Madrid Agreement)	WIPO	Under consideration
Patent Cooperation Treaty (PCT)	WIPO	1997
Treaty on the International Recognition of the Deposit of Micro-Organisms for the Purpose of Patent Procedure (Budapest Treaty)	WIPO	1997
Trade-related Aspects of Intellectual Property Rights (TRIPS)	WTO	1995
Union for the Protection of New Varieties of Plants	UPOV	1977

[2] About 100 US patents of South African origin are granted annually in the US Patent and Trademark Office (Department of Science and Technology, 2002).
[3] Act No. 38 of 1997, which also provided for the implementation of the Patent Cooperation Treaty in anticipation of South Africa's accession.

committees have been established to investigate certain defined areas, including indigenous knowledge systems (IKS) and the commercialization of IP. Some of these areas are also being examined in other initiatives, both within the Department of Trade and Industry (DTI) and in other government departments.

Patent legislation

Patents are governed by the Patents Act and by Regulations made under the Act, which deal with certain procedural matters. General patentability requirements are similar to those in most other jurisdictions. A patent may be obtained for an invention that is novel, involves an inventive step (i.e. is 'unobvious') and that can be used or applied in trade, industry or agriculture. The novelty requirement is absolute, so novelty is destroyed if, prior to filing a patent application, relevant information about an invention is made available to the public, anywhere in the world, in any manner.

An 'invention' is defined negatively, via a list of categories that are *not* considered to be an invention for the purposes of the Act. Excluded from patentability are discoveries; scientific theories; mathematical methods; literary, dramatic, musical or artistic works; schemes, rules or methods for performing a mental task, playing a game or doing business; and computer programs and the presentation of information. Furthermore, inventions that might encourage offensive or immoral behaviour, inventions contrary to well-established natural laws and medical methods of treatment are not patentable. Medicines and medical devices do, however, constitute patentable subject matter.

A patent is granted for a term of 20 years from the date of filing a complete patent application, subject to the payment of prescribed renewal fees.

A Patents Amendment Bill has recently been released for public comment. In addition to proposing certain technical changes, it contains clauses introducing a provision based partly on the US Bolar provision. It is proposed that research and development (R&D) of patented inventions, but not commercial use, should be permitted during the term of the patent. This would allow subsequent manufacturers to be ready to enter the market immediately on expiration of the patent. In the absence of this provision, patentholders are effectively able to extend their patent term, due to the time required for others to develop and, where appropriate, register the patented product. The proposed provision would apply to all fields of technology and would not be restricted to the pharmaceutical and agrochemical sectors. The pharmaceutical industry is calling for a further amendment to enable the patent term of pharmaceuticals to run from the time of approval by the Medicines Control Council rather than from time of discovery, to make up for the regulatory delays that limit the time in which a company may exploit the patented drug exclusively (Ensor, 2002).

'Life' patents in South Africa

Patentability of biological inventions

In dealing with the patentability of biological inventions, the Patents Act adopts similar wording to the corresponding EPC provision (Section 25(4)(a) and EPC article 53(b), respectively). It states that:

> A patent shall not be granted for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the product of such a process.

While microbiological processes and their products are therefore clearly patentable, exactly what constitutes a 'microbiological process' or a product thereof, and what the situation is regarding the patentability of other living material, is less clear, because the Act does not define key terms such as 'variety', 'essentially biological' or 'microbiological', and the courts have not been called upon to interpret these terms. Guidance is therefore obtained from other jurisdictions whose legislation contains similar provisions, the European Patent Office (EPO) Guidelines for Examination being a particularly useful source in this regard. A 'microbiological process or the product of such a process' is thus expected to include microorganisms as well as processes involving their use and utility. The Act therefore appears to offer protection for microbiological organisms and processes, as well as for processes producing transgenic plants or animals, and for the products of such processes (provided there is a sufficient degree of human intervention), unless the plant or animal product of such process is a variety.

It is interesting to note that a precedent for the patenting of plant material in South African law can be found in the repealed Patents Act No. 37 of 1952. Prior to the introduction of the Plant Breeders' Rights Act No. 22 of 1964, new plant varieties were patentable. It might be argued that this provides evidence for the patentability of living material under South African law. An alternative interpretation, however, holds that the express provision for the patenting of plant material implies that inventions in the field of animal life are not patentable, such inventions having been excluded from the scheme of the repealed Patents Act (Van der Merwe, 1993). Nevertheless, this debate is likely to be less important than the persuasive authority of other jurisdictions, in the event of South African courts being called upon to decide the question of the patentability of living material, taking into account that the Act concerned has been repealed and that the relevant South African legislation now in force is based on European legislation.

South African patents have been granted for various biotechnological inventions, including genetically modified (GM) microorganisms,

plants and animals. While none of these patents has been challenged in the courts, and their validity could therefore still be brought into question, it is generally accepted from a practical perspective that at least some of these patents are valid. The fact that biotechnology companies continue to file patents for inventions dealing with living material is evidence that there is a degree of confidence in the protection offered by the legislation (G. Tribe, patent attorney, Spoor and Fisher, Johannesburg, 1996, personal communication).

Deposit of samples

South Africa acceded to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in 1997. Although prior to this the Patents Act provided for the deposit of samples of microorganisms, where a complete specification claimed as an invention a microbiological process or product and the microorganism concerned was not available to the public, the relevant section was not operative until recently. None the less, in practice it was fairly common for deposit to take place for microbiological inventions in appropriate cases even prior to this requirement being mandatory, in order to satisfy the sufficiency requirement for patentability (S. Clelland, patent attorney, Spoor and Fisher, Johannesburg, 2002, personal communication).

Article 27.3(b) of TRIPS

South Africa is not advocating the reopening of negotiations on Article 27.3(b), but is in the process of defining how the country's interests can best be promoted and protected, if the section were to be renegotiated. Stakeholders, including DTI, Department of Agriculture (DoA), Department of Environmental Affairs and Tourism (DEAT), civil society and the private sector will be consulted (P. Krappie, DTI, Pretoria, 2001, personal communication).

Patent filing

Over 10,000 patent applications are filed annually in South Africa (approximately half of these taking priority from other countries), and about 4000 patents are issued per year. The South African patent system offers the option of a two-stage application procedure. A provisional application may be filed up to 12 months before filing a complete application (with an additional 3-month grace period available). This gives an effective date for the invention from which priority can be

claimed (i.e. novelty is considered only up to this date), and allows the inventors to develop the invention further before finalizing the content of the complete specification and/or filing overseas. Alternatively, a complete application may be filed in the first instance. As a member of the Paris Convention, priority can be claimed for subsequent filings in other Convention countries from a South African patent application, within 1 year of the original filing.

It is comparatively cheap to file patent applications in South Africa, with the cost of preparation of a specification and filing by a patent attorney usually coming in below US$1000.[4]

Companies and Intellectual Property Registration Office

CIPRO was established in 2002, in a merger of the former South African Companies Registration Office and the South African Patents and Trade Marks Office.[5] It is an independent business agency of the DTI, situated in Pretoria, and managed by a Chief Executive Officer overseen by a Board. CIPRO sees itself as providing a gateway to economic participation, both by South African citizens and foreigners doing business in South Africa. One of its early objectives is to ensure that it becomes more accessible to its users and potential users, by increased use of electronic media, education programmes and a Customer Contact Centre. It also aims to expand the role of South Africa in the IP sphere and to facilitate improved confidence of international investors by ensuring that South Africa is viewed as a country that gives due recognition to IPR (www.cipro.gov.za).

Patent applications are filed through the IP Division of CIPRO, which will be headed by a Registrar of IP.[6] The patent filing system is relatively unsophisticated. It is a non-examining office, only partially computerized, and equipped with neither the human resources nor the technology required for proper examination of the merits of a patent application. The Registrar therefore conducts only a formal examination, ensuring that all necessary procedural and administrative requirements have been satisfied. The onus for performing novelty searches therefore lies with the applicant. The lack of examination means that there is less certainty about the validity of a South African patent than there would be for a patent that has undergone examination. None the less, a registered patent is considered prima facie valid.

Efforts are underway, in cooperation with international organizations such as the World Intellectual Property Organization (WIPO) and the EPO to address this, but the first priority is to ensure that existing functions

[4] At the prevailing exchange rate at the time of writing, US$1 is equivalent to approximately R10.
[5] In the past, these offices occupied the same building, but operated completely separately.
[6] The position is vacant at the time of writing, and has been for some time.

operate optimally, to which end extensive upgrading of the information systems is taking place to facilitate improved recordkeeping (including an electronic *Patent Journal*), search facilities and online applications (expected to be in place by 2004). Down the line, options under discussion include the introduction of limited examination (in technical fields where local expertise is available and a critical mass of patent applications are filed at CIPRO) and the acceptance of search reports from other approved patent offices. CIPRO will endeavour not to attempt to 'reinvent the wheel' where simple solutions might already exist (P. van Stavel, Executive Manager, IP, CIPRO, Pretoria, 2002, personal communication).

The courts

The validity of a patent is ultimately determined by the courts, which have generally proved competent in this regard. A party wishing to challenge the validity of a patent therefore bears the onus of proving invalidity in the courts. Patent litigation is instituted in the Court of the Commissioner of Patents. The commissioner is a judge of the Transvaal Provincial Division of the High Court of South Africa (TPD). Appeals to decisions of this court can be made to a Full Bench of the TPD and thereafter to the Supreme Court of Appeal. The courts have generally adopted a pro-patentee attitude, taking a resolute stand against infringement and copying.

Litigation takes place at the level of the High Court, since South Africa has a 'split bench' legal system, and therefore it is costly. As a result, small companies can rarely afford to litigate and even large companies with the necessary resources are often reluctant to do so, deterred by the high degree of technical expertise involved and the difficulty in finding expert witnesses.

Compulsory licensing

The Patents Act provides for the granting of compulsory licences in respect of dependent patents and in cases where patent rights have been abused. Situations are listed that give rise to the presumption that an abuse of patent rights has occurred. An interested party may apply for a compulsory licence, which will be granted if the commissioner determines that any of the listed situations exist. In practice, this is rarely invoked. Partly because of this, in an attempt to ensure a supply of affordable medicines, a controversial provision allowing parallel importation of patented medicines was introduced by the Department of Health into the Medicines and Related Substances Act (Act No. 101 of 1965) in 1997, notwithstanding anything to the contrary contained in the Patents Act.

This became the subject of a high-profile lawsuit, which reached the courts in 2001. Thirty-nine multinational pharmaceutical companies insti-

tuted legal proceedings against the South African government, challenging the relevant provision, but in the midst of a national public outcry and international condemnation due to the country's high HIV/AIDS infection rates, the lawsuit was dropped. Opinion remains divided over whether the section concerned was necessary to enable the government to protect public health, or whether the provisions of the Patents Act and of TRIPS (such as those dealing with compulsory licensing and allowing countries to adopt measures necessary to protect public health) were in fact adequate. Some argue that this was a political move by the government, which could undermine the legal system, but the stance of the South African government and the retreat of the corporations have been hailed throughout most of the developing world as a victory in the ongoing quest for health equity.

Copyright

Copyright is governed primarily by the Copyright Act. Works eligible for copyright protection under the Act include: literary works; musical works; artistic works; cinematograph films; sound recordings; broadcasts; programme-carrying signals; published editions; and computer programs.

Copyright vests automatically in the author for original eligible works reduced to material form. There is no system of registration for most copyright works, (an optional registration system exists for cinematograph films) and it is not mandatory to mark copyright works, although this is often done in practice. The author is usually the first owner of copyright in the work concerned. Exceptions for specified categories of works include certain works made in the course of employment and certain works that are commissioned. Copyright subsists for a period of the life of the author plus 50 years from the end of the year of the author's death for literary, musical or artistic works other than photographs. For cinematograph films, photographs and computer programs, the duration is 50 years from the end of the year in which the work is made available to the public.

South Africa is a member of the Bern Convention.

Trademarks

The Trade Marks Act sets out the requirements for trademark protection. Trademarks can be used for goods or services in order to distinguish those goods or services from similar goods or services used by another person. The Act defines a mark as:

> any sign capable of being represented graphically, including a device, name, signature, word, letter, numeral, shape, configuration, pattern, ornamentation, colour or container for goods, or any combination of the aforementioned.

The Act also provides for collective marks to distinguish the goods and services of members of an association from those of others, and for certification marks, which designate goods or services of a particular origin, material, mode of manufacture or performance, quality, accuracy or other characteristic.

The proprietor's right to use a registered mark can be limited in certain cases. For example, common law rights may be obtained through use of a mark in South Africa, and the user of such a mark may challenge the registration of a proposed mark or the use of a registered mark if it relates to similar goods or services. Furthermore, well-known marks, such as those with an international reputation, are afforded some protection, and an attempt to register such a mark is unlikely to be successful. While registration is not a prerequisite for use of a trademark, it offers several benefits, including deterring potential infringers and making it easier to restrain actual infringers.

Goods and services are classified into classes according to the Nice Classification of Goods and Services, and an applicant must file a trademark application in each class in which protection is sought.

Trademark registration takes place through the IP Division of CIPRO. All applications are examined to ensure that the requirements for registration are met and that there are no conflicts with current registered marks or applications. Once accepted, the mark is publicized in the *Patent Journal* and third parties have a period of 3 months to oppose the registration. Registration lasts for 10 years from the date of application and may be renewed indefinitely for further 10-year terms, subject to the payment of prescribed renewal fees.

South Africa is not a member of the Madrid Convention, but accession is under consideration (Du Plessis, 2002).

Designs

The Designs Act provides for the registration of industrial designs. Design registration protects the shape and appearance of articles. Two types of designs are provided for: (i) aesthetic designs are applied to articles with features that appeal to and are judged solely by the eye, for pattern, shape, configuration or ornamentation; and (ii) functional designs are applied to articles that have features necessary to the function performed by the article, for pattern, shape or configuration, including integrated circuit topographies and mask works. The appearance of an article may be registered as both an aesthetic and a functional design.

To qualify for registration, an aesthetic design must be new and original, while a functional design must be new and not commonplace in the art. The term of protection is 15 years for aesthetic designs and 10 years for functional designs, subject to the payment of prescribed renewal fees.

Plant variety protection

Legislation

Plant variety protection is governed by the Plant Breeders' Rights Act. In 1996 amendments brought the Act into compliance with the 1991 revisions of the International Union for the Protection of New Varieties of Plants (UPOV), which South Africa has signed, but not ratified.[7] A plant variety is eligible for protection if it is new, distinct, uniform and stable, and its denomination (generic name) complies with prescribed requirements. A new variety is developed when important new characteristics are brought about by alteration of existing characteristics through selection and breeding. The term of protection varies according to the type of plant for which protection is sought, being 25 years for vines and trees, and 20 years for all other varieties. Varieties that meet the requirements from all plant genera and species may be protected. Prior to the 1996 amendments, the minimum term of protection was 15 years, and Regulations under the Act stipulated which plant species were registrable (this list being changed from time to time).

The owner of a plant breeder's right has the exclusive right to exploit a protected plant variety and can exclude others from producing, selling, importing or exporting its propagating material. Private, non-commercial or experimental use of a protected variety for further breeding does not fall within the ambit of the protection conferred by the Act. Changes brought about by the amending Act include the introduction of the concept of an 'essentially derived variety', commercial use of which requires the consent of the owner of the initial protected variety, and the extension of protection to harvested material in cases where the breeder is unable to obtain remuneration rightfully on the propagating material.

The Act makes provision for a breeder's exemption and farmer's privilege, by providing that certain activities undertaken using legitimately acquired propagating material will not constitute infringement of another party's plant breeder's right. These include development of a different variety, *bona fide* research, private or non-commercial use and use by farmers of harvested material (Dold, 1982; Van der Walt, 1996; W. Loubser, General Manager, SANSOR, Pretoria, 2002, personal communication).

Current legislation is silent on the concepts of farmers' rights. DoA, however, acknowledges that recognition of farmers' rights is important for promoting the conservation, management and sustainable use of

[7] It appears that a political decision has been made not to ratify UPOV 1991, but this does not seem to have any practical effect because of the legislative amendments that have been implemented.

plant genetic resources for food and agriculture and intends to address this. As yet, little progress has been made in giving substance to these principles in order to integrate them into the legislative framework, but it is likely that a working group of stakeholders will be convened to draw up a discussion paper to serve as the basis for a draft Bill (DoA, Pretoria, 2001, personal communication).

Application

Plant breeders' rights are administered by the Directorate of Genetic Resources in the DoA. A large proportion of registered varieties is held by South African plant breeders, who also register their varieties in appropriate overseas markets.

Plant variety protection has undoubtedly been beneficial to the seed industry and formal farming sector, by:

- stimulating private investment in plant breeding, which has increased considerably since the introduction of plant breeders' rights;
- giving local breeders the opportunity to benefit from wider access to new varieties released internationally;
- providing a source of funding from royalties on protected varieties for public research institutions; and
- allowing farmers and consumers to benefit from increased crop yield and improved crops resulting from new varieties (Van der Walt, 1996).

Some concern has been expressed that enforcement mechanisms are inadequate. Enforcement is by civil litigation between breeder and infringer and is not considered to be very effective against seed piracy, due to insufficient penalties for wilful infringement (B. Koster, patent attorney, Findlay and Tait, Cape Town, 2002, personal communication).

Protection of indigenous knowledge systems

The process of enacting legislation to promote, develop and protect IKS in South Africa has been a protracted one. An initial draft Bill was tabled in Parliament in 1997, with a new draft appearing in 2000 but never tabled, both of these proving inadequate for different reasons. The first was a lengthy document, which proposed that indigenous knowledge (IK) be protected via existing IPR, by extending the definition of IPR to include IK and amending relevant legislation accordingly. The implications of this were either that existing IPR would have to be modified, most likely in contravention of some of the international agreements to which South Africa is a party, or that most forms of IK would

not qualify, as they would fail to meet the stipulated requirements for existing forms of IP protection. The second draft was, in contrast, remarkably concise, but contained insufficient substance to promote the objectives that the Bill aimed to achieve, as a result of which it was not taken further.

In 2000, public hearings on the initial draft Bill were held around the country, to assess the extent to which it was able to meet the needs of IK holders, in light of critical comments that indicated that further research and review was needed to address the concerns that had been raised (Parliamentary Portfolio Committee on Arts, Culture, Science and Technology, 2000). A reference group has subsequently been convened to redraft the Bill, informed by a draft policy and the submissions to the public hearings.

The absence of clear policy to direct the earlier attempts at legislation perhaps explains some of the shortcomings of the previous draft Bills. It would appear that the pace of these efforts was accelerated due to the importance ascribed to IKS and an over-enthusiasm to legislate quickly, but that this was too ambitious and hence unrealistic.

Biodiversity and access to genetic resources

South Africa contains an immense wealth of indigenous genetic diversity, including the Cape Floral Kingdom, and a very high proportion of endemic species, especially of vascular plants. Huge potential exists to exploit this biodiversity for medicinal use, horticultural applications and as forage plants. The White Paper on Conservation and Sustainable Use of South Africa's Biological Diversity (Department of Environmental Affairs and Tourism, 1997) sets out national biodiversity policy. Specific policy objectives are addressed on access to genetic resources and benefit-sharing, traditional knowledge and beneficiation of biodiversity. Access to genetic resources is currently controlled by legislation at the provincial level. All provinces have ordinances that govern the movement of non-human biological material via permit systems.

At the national level, DEAT has for some time been involved in drawing up legislation in the form of the Biodiversity Bill, which has now been released for public comment. Existing legislative models from around the world were extensively consulted, including the African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resource in Relation to International Law and Institutions, but the Bill is not based on any particular precedent. The legislation will govern activity concerning all South African sovereign biological resources other than human material. It is intended to establish a framework for the

rights and the obligations of both the owners of genetic resources and those desiring access, including the matters of use, access for research purposes, bioprospecting and commercialization. The goals of the legislation are:

1. To give legal effect to the goals of the White Paper, especially those relating to conservation, sustainable use, access to genetic resources and benefit-sharing arrangements;
2. To provide a uniform legal framework setting national norms and standards for the management of biodiversity;
3. To improve and harmonize relevant existing legislation on biodiversity management and to block loopholes;
4. To give legal effect to the relevant international conventions to which South Africa is a party.

Amongst other things, it is envisaged that: (i) the Bill will distinguish between academic research and bioprospecting, the latter requiring an appropriate access and benefit-sharing agreement to be in place; (ii) a Bioprospecting Council will be set up to evaluate applications and agreements; and (iii) principles will be laid down for the development of *sui generis* community rights, although it is not intended that the Biodiversity Bill will give content to such rights, this being the responsibility of the Department of Science and Technology (G. Willemse, DEAT, Pretoria, 2001, personal communication).

Intellectual Property Management in South Africa

Overview

IP management remains for the most part a somewhat arcane field, but awareness is growing and experience and capacity in the handling of IP are gradually being built up, in government, business and academia.

Since 1998, and even earlier for certain institutions, most of the major research organizations (universities and science councils) have developed IP policies and appointed staff to manage their IP and educate researchers on the importance of protecting IP. In general, institutions have followed different routes for managing their IP. Some have set up dedicated offices, some have established associated companies (fully or partially university-owned), some utilize outside consultants and there remain some that have yet to take steps to deal with these issues. Ownership of IP usually, but not in all cases, vests in the employing institution, which may license or assign its rights to an external organization or company, often under a research sponsorship agreement. Any proceeds that accrue to the institution as a result of commercial exploitation of IP are generally shared with the inventing researchers.

Problems faced

Even for those institutions that have been investing on an ongoing basis in setting up infrastructure and supporting training, patenting and marketing costs in an effort to build capacity in IP management, the benefits are slow in coming and there remain numerous barriers to be overcome, including the following.

- The importance of IP management is not well understood by many of the individuals dealing with it, in all sectors (government, academia and even business). The objectives of a technology transfer office are often questioned, both by researchers and funders. Misconceptions abound as to the potential financial gains that these activities may generate, as well as the time and investment needed to show returns, and the broader potential socio-economic value that could be derived is frequently overlooked.
- Patenting is a high-cost endeavour, particularly overseas, and this is exacerbated by an unfavourable exchange rate. Few institutions have the resources to cover the costs of international patent filing. The weak currency also limits opportunities to benefit from international training and networking opportunities.
- Capacity is limited and there are few individuals with experience as technology-transfer professionals. Mentors and training opportunities are limited, with the result that practitioners are forced to learn by trial-and-error rather than by means of good practice.
- Due to the small base of research funding in the country, the flow of invention disclosures is weak and is unlikely to increase soon without a substantial injection of funding into the system.
- A very high percentage of research funding comes from external sources (i.e. other than government agency grants), estimated at almost 70% of the total research funding of the main research universities, and is subject to conditions that may restrict an institution's freedom to exploit any IP developed from such research.
- International research collaborations are often structured so as to ensure that the value-adding steps leading to protectable IP are performed overseas, due to a real or perceived lack of capacity or resources in South Africa. Since royalty payments are typically tied to patents, the early stage South African contributions often do not benefit from downstream commercial earnings.
- Many inventions emanating from South African institutions are aimed at solving Africa-specific problems. Often, those who are intended to benefit will be unable to afford to pay for access to the technology concerned. Without the prospect of future income flows, institutions cannot justify using internal resources to cover the costs of getting the technology to market.

- An 'innovation chasm' has been identified, representing a gap between knowledge generators, such as research institutions, and the market (Department of Science and Technology, 2002). Support for new business formation is very limited. The financial institutions and venture capitalists are risk-averse and therefore reluctant to get involved at an early stage. However, without early stage funding, many good ideas will not be developed further.

Possible interventions at the institutional level

Several interventions have been identified to address these difficulties at the institutional level.

- Adequate human and capital resources must be devoted to supporting these activities in institutions with sufficient research output. Technology transfer must be recognized as an emerging profession, individuals must receive professional training and proceed and be treated accordingly as professionals.
- Relevant institutional policies must be aligned and consistently applied in order to avoid conflicts, such as those dealing with IP, private work, ethics, conflicts of interest and sponsored research (including cost recovery). Strong institutional ethics committees and review boards have a vital role to play in regulating interactions that push the boundaries of traditional relationships between universities and industry.
- Networks must be cultivated through which knowledge and experience can be shared and synergies capitalized on. This might involve joint training and education opportunities, capacity building, transfer of skills and provision of services, and new partnerships between organizations.
- Key indicators must be determined and activities benchmarked against both international and local standards. The commercial and social impacts of these activities should be publicized.
- More university IP teaching and research programmes are needed to provide a stronger academic grounding to underpin, inform and enrich the national IP system.

In acknowledgement of these needs, the Southern African Research and Innovation Managers' Association (SARIMA) was established in February 2002. Its objectives include professional development of those involved in managing research and the creation of intellectual capital; promotion of best practice in the management and administration of research and the use of intellectual capital to create value for education, public benefit and economic development; advocacy of appropriate national and institutional policy in support of research and generation of intellectual capital; and advancement of science, technology and innovation (SARIMA, 2002).

Membership is open to institutions and individuals active in research and innovation support (public, private and academic). SARIMA has links with several South African and international organizations with related and complementary objectives. The organization potentially offers a strong platform from which to drive research and innovation management activities, including technology transfer, nationally and regionally.

It must be noted that many disparities continue to exist between institutions, often an unfortunate legacy of past government policy. It would not be feasible for all institutions to run their own technology transfer operations, as many lack critical mass in research. There are, however, opportunities to be explored for sharing of skills and resources and for tapping into existing expertise in other organizations.

National issues

Institutional activities have developed in the absence of any national policy on the matter. Recently, discussion has been initiated in government on the topic of exploitation of IP generated from state-funded research, including the introduction of a national policy (Department of Science and Technology, 2002). Currently, there is no clarity regarding ownership of IP developed out of research funded by the government. Such funding takes many forms and is distributed through a variety of organizations and agencies, some of which have clear policies (not necessarily consistent with one another), while others deal with IP matters on an *ad hoc* basis, if at all. As government agencies become more aware of IP, they are tending to assert their rights in IP generated from research they fund more aggressively than in the past. For example, ownership of IP may be stipulated as a condition of funding (even where the agency or department concerned has no interest in exploiting the IP other than for its own use), or the funding agency may be entitled to share in any revenue accruing from successful exploitation by a research institution. This trend appears to run contrary to practice in many other countries, most notably the USA, whose Bayh–Dole Act is given credit for playing a vital role in stimulating the economy by, among other things, conferring the right on recipients of federal research funding to own the IP arising out of such research, coupled with the obligation to exploit the IP. The development of a viable policy framework in South Africa will have to be informed by a combination of the realities of the local situation and by models that have proven successful overseas, such as Bayh–Dole.

It must be borne in mind that the US successes largely attributed to Bayh–Dole have come out of a vastly different research environment. Despite extensive interactions with and substantial support from industry, the bulk of US university research funding still comes from federal and state sources and, as such, falls under the ambit of Bayh–Dole. The

relatively small proportion of South African university research funding that would be covered if an equivalent statute were enacted here would significantly lessen its impact. However, by setting out principles to govern the relationships between government, universities and business, such legislation could provide clarity and set standards for the interactions between research institutions and the private sector. Care will have to be taken to ensure that such a policy is not excessively prescriptive, to avoid restricting these relationships, bearing in mind the heavy reliance of public research on private sector funding.

An enabling policy framework would go a long way to support IP management by institutions. Coordinated input from stakeholder government departments and agencies will be needed to design a coherent scheme and ensure alignment with other relevant legislation and policies. Some of the content of such a policy might include the following.

- A clear position should be taken on ownership of IP from government-funded research and should apply to all publicly funded research. It is submitted that putting ownership and responsibility for exploitation in the hands of institutions, coupled with incentives for exploiting it in such a way as to promote government imperatives, would allow government to achieve its objectives, while at the same time offering a higher probability of success, than if government were to attempt to retain ownership.
- Incentives could include government support for IP management activities of institutions that:
  - develop innovations that solve national problems, contribute to poverty alleviation or promote competitiveness;
  - have a good record of licensing to small or medium enterprises or historically disadvantaged businesses;
  - commit to capacity building and sharing resources with historically disadvantaged institutions.
- Government must have a mechanism to ensure optimal utilization of research results from state-funded projects (including safeguarding its own rights to access such results), which need not entail government ownership of such results.
- Researchers must be rewarded for innovative work by sharing in any proceeds that flow from exploiting their innovations.

Government could play further vital roles by instituting support programmes for training and operating costs, and by tabling relevant issues and marshalling international support (political, technical and financial) in international fora, such as those provided by WIPO, the World Bank and WTO, in an attempt to level the playing field for South Africa and other developing countries wishing to participate in the knowledge economy and bridge the knowledge gap (Wolson, 2002).

The National Advisory Council on Innovation has been tasked with bringing together the key role-players to set in motion a process for formulating appropriate policy.

The Impact of Intellectual Property Rights on Agricultural Biotechnology Development in South Africa

Brief summary of agricultural biotechnology in South Africa

South Africa has fairly well-developed expertise in biotechnology research (including third-generation biotechnology). However, research efforts have suffered from a lack of coordination and prioritization, and there remain few locally developed biotechnology products and processes that have reached the market. In an attempt to address this shortcoming, a National Biotechnology Strategy was formulated in 2001 and is in the process of being implemented. Two Biotechnology Regional Innovation Centres have been funded and a third will receive funding in 2003. The year 2001 also marked the launch of the first dedicated South African biotechnology venture capital fund. These recent developments illustrate a new interest in biotechnology in both the public and private sectors. Biosafety legislation was enacted in 1997 and implemented in 1999 (Act No. 15 of 1997). Four GM crops, listed in Table 9.3, have been approved for commercial release (Webster and Koch, 1998; AfricaBio, 2002).

The role of intellectual property rights

While acknowledged that there is room for improvement, the national IP regime is not regarded as posing an obstacle to the uptake of agricultural biotechnology in the country, and in certain respects is considered conducive to progress by offering a functional framework for protection of biotechnology products and processes. There is some concern that accessing proprietary technology, mainly from large transnational corpo-

Table 9.3. GM crops approved for commercial release in South Africa (AfricaBio, 2002).

Crop	Year approved
Insect-resistant cotton	1997
Insect-resistant maize	1998
Herbicide-tolerant cotton	2000
Herbicide-tolerant soybeans	2001

rations, will raise the costs of developing local agricultural biotechnology applications, as well as of imported seed. However, it is of interest to note the high adoption rate of insect-resistant cotton by small-scale cotton farmers, estimated to be as high as 90%, up from 7% in the 1997/98 season, despite a higher seed cost and technology fee when compared to conventional seed. Pesticide savings are seen as the greatest benefit, followed by increased yield (Kirsten *et al*., 2002). This seems to provide evidence that where greater benefits are apparent, added costs will not be a deterrent to uptake of the technology. It also demonstrates that the opportunities offered by agricultural biotechnology need not be confined to large-scale commercial farmers.

The question of obtaining licences for platform technologies on affordable terms to enable commercialization of local technology is more complicated, and there are concerns that this might impede development. Also, extensive capacity building will be needed to equip South Africa with sufficient specialist legal and technical skills to negotiate the increasingly complex and evolving international IP landscape, particularly in respect of biotechnological inventions, as the existing skills base is too small to do this effectively.

The role of non-intellectual property factors

Expert IP management skills will undoubtedly be a prerequisite for the roll-out of agricultural biotechnology applications, but it is important to remember that this is only one of several considerations in this regard, and cannot be viewed in isolation. Other relevant factors include the state of the national R&D system, biosafety regulation, public acceptance of GM crops and the financial and political environment.

State of the national research and development system

The country's R&D system is under stress on a number of fronts. Current funding levels at 0.7% of gross domestic product (compared with a 2.15% OECD average) are too low to promote competitiveness, and the profile of researchers is severely skewed in terms of age, race and gender, which poses a threat to the sustainability of the system. This is recognized in South Africa's National R&D Strategy and interventions have been proposed to address the problems, but it will clearly take time for implementation to make an impact (Department of Science and Technology, 2002). Heavy reliance on private sector funding of research in universities and science councils, much of this international, sometimes leads to institutions and researchers feeling obliged to accept unfavourable contractual terms or to enter into collaborations that might not offer optimal benefits for the local researchers. Before any

meaningful benefits from the exploitation of IP can be expected, it will be necessary to strengthen the national R&D system, to ensure that the current knowledge base is maintained and ultimately strengthened and to provide an adequate and ongoing flow of invention disclosures. Policy dealing with IP management should therefore build in measures to assist in accomplishing this goal.

Biosafety

Prior to the implementation of legislation, biosafety was regulated by the South African Committee for Genetic Experimentation (SAGENE), an advisory body of experts in different fields relevant to genetically modified organism (GMO) work set up in 1979. The current legislation, implemented in 1999, regulates all stages of the handling of GMOs, including importation, production, release and distribution. While this is regarded as a vital step forward in creating an environment conducive to growing an agricultural biotechnology industry in the country, doubts have been expressed about DoA's capacity to implement it efficiently, due to insufficient personnel with the necessary expertise and experience. This has led to delays in processing applications. Concerns have also been expressed that environmental risk liability issues and public participation are not adequately provided for (Mayet, 2001; AfricaBio, 2002; F. Joubert, attorney, Edward, Nathan and Friedland, Johannesburg, 2001, personal communication).

Two recent developments illustrate some of the dissatisfaction with the current framework. One of these involves legal action taken by an environmental watchdog organization against the Minister of Agriculture and others for failing to disclose information on GM crops, and the other a debate in the Parliamentary Portfolio Committee on Environmental Affairs and Tourism, in which it was claimed that Parliament was insufficiently informed when the legislation was passed, and calling for a reassessment of the Act and Regulations (Gosling, 2002; Yeld, 2002).[8]

It is too early to predict whether the biosafety framework will undergo major changes. While delays in processing applications have been experienced, and while the system could be improved in a number of ways, there have been no problems or scares regarding the handling and release of GMOs. Those active in the agricultural biotechnology sector regard the legislation as a vast improvement over having no regulation at all and believe that despite its flaws, there are sufficient safeguards in place to minimize potential risks.

[8] Biosafety is the responsibility of DoA and not DEAT.

Public acceptance of genetically modified food

Public understanding of the issues surrounding GM food remains very limited, and the average consumer is unlikely to be sufficiently informed about relevant issues to formulate an opinion either for or against, despite the presence of organizations both promoting and opposing the technology. However, as more GM food products start to enter the market, awareness will increase and it is not clear at this stage what level of acceptance will develop. The recent high-profile rejection of GM food aid by countries in the region suffering severe drought and facing famine can be expected to play a role in shaping public opinion in South Africa, which will have a significant impact on the application of agricultural biotechnology.

Political and economic environment

The local investment community remains very conservative, and it is expected that international investment will be needed to create a vibrant biotechnology sector in the country. Foreign direct investment (FDI) into South Africa remains low, despite the political transformation and economic restructuring of recent years, which have created many of the conditions regarded as essential to attracting FDI. Some of the factors said to limit FDI include the following.

- The trade union movement is very influential and the labour market is considered inflexible, limiting growth prospects.
- Exchange control regulations remain in place, although they are gradually being eased. Government has repeatedly stated its commitment to the complete abolition of exchange control, but has set no time frame for this.
- The currency is volatile, with frequent fluctuations in the exchange rate in response to both internal and external events, particularly developments affecting other emerging markets.
- While the local political environment is stable, volatility in neighbouring countries is perceived as a cause for concern of potential foreign investors, who fear that this instability might spill over into South Africa.

Conclusion

The emotive debates around IPR often cloud the fact that IP is merely a tool to facilitate technological progress and not an end in itself. In the South African context, where opportunities exist to exploit a fairly sophisticated infrastructure and research base relative to other developing countries, the key challenge lies in ensuring that technology can be

harnessed to improve lives and livelihoods in a sustainable manner. While effective handling of IP matters will not be sufficient to ensure successful technology deployment, mismanagement of IP could very likely prevent it. Despite its shortcomings, the national IP regime is in many respects conducive to promoting the progress of science and technology in general, and biotechnology in particular, but the existing framework must now be extended to establish new forms of rights for the protection of IKS (indigenous knowledge systems) and biodiversity. At the same time, expertise and partnerships must be built and supported, both in science and technology and in IP matters, in order to enable South Africa to occupy a stronger negotiating position in international fora, to access cutting-edge technology on the best possible terms and to develop indigenous innovative technology.

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10

Australia

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Current Status of Intellectual Property Laws

Australia is a federation, or commonwealth, of eight states and territories, each with its own court system and parliament. Overarching the commonwealth is a national Parliament, which has paramount legislative power on subjects that are listed in the federal Constitution. The Constitution dates from the turn of the century. Section 51 (xviii) of the Constitution confers power upon federal Parliament to legislate with respect to 'copyrights, patents of inventions and designs and trademarks'. A potential problem for the federal Parliament was that new categories of intellectual property rights, such as plant breeders' rights, are not listed in section 51 (xviii) of the Constitution.

This issue was considered by the High Court of Australia in Grain Pool of Western Australia v. Commonwealth of Australia and Another (2000) 46 Intellectual Property Reports 515. That case concerned a statutory grain marketing authority in the state of Western Australia, which was alleged to have infringed the plant variety rights of the second defendant, by exporting its variety of Franklin barley. The Western Australian authority claimed that the Plant Breeder's Rights legislation of the federal Parliament was invalid, because plant breeder's rights were not mentioned within the Constitution. The High Court rejected this submission, first on the basis that section 51 (xviii) of the Constitution was capable of expanding to embrace new developments in technology and also that since Australia was a signatory to the International Union for the Protection of New Varieties of Plants (UPOV) Conventions of 1978 and 1991, the Plant Breeder's Rights legislation could also be grounded on the 'external affairs' power in section 51(xxix) of the Constitution.

 Intellectual Property Rights in Agricultural Biotechnology. Second Edition (eds F.H. Erbisch and K.M. Maredia)

Relevant federal intellectual property (IP) legislation includes the Designs Act 1906, Copyright Act 1968, Circuit Layouts Act 1989, Patents Act 1990, Plant Breeders' Rights Act 1994 and Trade Marks Act 1995. Australia's IP statutes were originally largely re-enactments of equivalent British statutes, but over the years they have been refashioned in line with Australia's national requirements, as well as its international IP obligations. Another significant federal statute with implications for IP is the Trade Practices Act 1974, which contains a comprehensive code proscribing unfair competition. Thus, infringement cases typically combine claims under the relevant intellectual property statute and allegations of 'misleading or deceptive conduct' in breach of section 52 of the Trade Practices Act 1974.

Since its creation in 1976, the Federal Court of Australia exercises jurisdiction in relation to federal statutes. Before this date, jurisdiction in IP matters was exercised by State and Territory Courts. Since 1976, litigants have had the choice of initiating litigation in State or Federal Courts, although, in practice, the Federal Court of Australia is increasingly becoming the preferred forum. Confidential information and trade secrets are protected under common law, through actions in the State and Territory Courts.

Australia is a signatory to all the major IP conventions and is a member of the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

Australian industrial property statutes are administered by IP Australia, with the exception of the Plant Breeder's Rights Act 1994, which is administered by the federal Department of Agriculture. Copyright matters fall within the jurisdiction of the federal Attorney General's Department.

Recent and Proposed Changes in Intellectual Property Rights Laws

The Commonwealth Parliament has been progressively reviewing all of Australia's IP laws. The Patents and Trademarks Laws were comprehensively updated by new laws in 1990 and 1995, respectively. The Plant Varieties Act 1987 was replaced by the Plant Breeder's Rights Act 1994. The Copyright Amendment (Digital Agenda) Act 2000 introduces a legislative regime to deal with copyright in digital works. The Patents Amendment (Innovation Patent) Act 2000 creates a utility model-type system for simple patents.

Australia was a founding member of the WTO and, consequently, a signatory to the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) (Blakeney, 1996a). In conformity with its obligations under the WTO Agreement, the Commonwealth

Parliament has passed three Acts to bring the country's IP laws into conformity with the TRIPS Agreement (Blakeney, 1996b). These were the Patents (WTO Amendments) Act 1974, Copyright (WTO Amendments) Act 1994 and the Trade Marks Act 1995. Of these statutes, the Patents and Trade Marks (WTO Amendments) Acts will probably have the greatest significance for agriculture. The principal changes effected by these Acts and the other recent IP laws are detailed below.

Patents Act 1990

On 30 April 1991 a new law, the Patents Act 1990, repealed and replaced the previous Patents Act 1952. The new law was passed as a result of a review of the patents legislation by the Industrial Property Advisory Committee (1984). The new Act was designed to simplify procedures to make patenting more accessible to non-experts. Under the new law the assessment of novelty and inventiveness was changed from the benchmark of national prior art to a standard of global prior art and publication. Additionally, a 'whole of contents' approach is taken to the assessment of novelty, in that the entirety of a specification will be examined and not just the claims made in an earlier application.

The High Court of Australia had ruled in National Research Development Corporation v. Commissioner of Patents (1959) 102 Commonwealth Law Reports 252 that agricultural or horticultural processes were capable of being regarded as a method of manufacture and consequently patentable. There has not yet been an Australian case on the patentability of plant varieties. The Patent Office has acknowledged their patentability in its official notice on the requirements for applications for patents of living organisms (1980) Australian Official Journal of Patents 1162 (see also APO, 1989).

A major change effected by the 1990 Act was in relation to the right of exploitation of patents. Under section 69 of the 1952 Act a patentee had the exclusive right to 'make, use, exercise and vend' the invention. Section 13(1) of the 1990 Act defines the right given by a patent as 'the exclusive rights, during the term of the patent to exploit the invention and to authorize another person to exploit the invention'. The term 'exploit' is defined in Schedule 1 to the Act to include: '(a) where the invention is a product – make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or (b) where the invention is a method or process – use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use'.

Finally, the 1990 Act adds a new form of infringement, consisting of the supply of a product, where use of the product would be an infringe-

ment, provided that use is the only reasonable use of the product and that use is in accordance with any instructions, inducement or advertisement given or published by the supplier, or, in the case of a non-staple product, that use is the one to which the supplier had reason to believe the receiver would put it (Patents Act 1990, section 117).

Patents (WTO Amendments) Act 1994

Patent term

The term of a standard patent granted after 1 July 1995 is extended by the amending Act to 20 years, instead of the previous patent term of 16 years, with the possibility of a 4 year extension for pharmaceutical patents. Additionally, patents granted under the previous law, which were due to expire after 1 July 1995, are to be extended to a 20-year term.

Compulsory patent licences

In the situation where a person, prior to the amending legislation, made a significant investment in anticipation of the expiry of a patent after 16 years, the amending Act provides for the grant of a compulsory licence to that investor. The preconditions for this licence are that: (i) the investment was made in good faith prior to 1 October 1994; (ii) no action by the applicant in preparation for the exploitation infringed the patent; and (iii) the applicant tried for a reasonable period, but without success, to obtain a licence from the patentee on reasonable terms. A similar extension is effected for licences that are due to expire at the end of the 16th year of the term of the patent. In both cases, the licence granted pursuant to these provisions:

- must not be exclusive;
- must not be assignable except in connection with the sale of a business;
- must be for a consideration agreed between the parties and if no agreement is reached, for a consideration determined by a court to be just and reasonable having regard to the economic value of the licence; and
- is subject to any terms stated in the order.

Where an existing licence is extended under these provisions, the court is entitled to take into account the terms and conditions of the previous licence. The compulsory licensing provisions do not apply in the case of pharmaceutical patents where the term could have been extended under the repealed provisions.

Infringement of process patents

The amending Act imports the provisions of Article 34 of the TRIPS Agreement, which provides that when infringement proceedings are commenced in relation to a patent for a process for making a product and the defendant alleges that the process used is different from the patented process, the court may determine that the product is made by the patented process, unless the defendant can provide evidence to the contrary. Such a determination is open to a court if it is satisfied that it is very likely that the defendant's product was made by the patented process and that the plaintiff has taken reasonable steps to find out the process actually used and has not been able to do so. The court is obliged to take proper account of the defendant's interests in having its trade secrets protected and is required to decide how a defendant can best adduce evidence to prove that its process does not infringe the patented process.

Plant Variety Protection Laws

In 1987 the Federal Parliament passed the Plant Variety Rights Act 1987, which conformed to the 1978 Act of the UPOV Convention. To bring the Australian law into conformity with the 1991 Act of the UPOV Convention, the 1987 legislation was replaced by the Plant Breeders' Rights Act 1994.

Scope of plant breeders' rights

Generally, the plant breeders' rights (PBR) conferred by the Plant Breeders' Rights Act 1994 (henceforth called the Act) are defined in section 11 as:

> the exclusive right to do or to licence the following acts in relation to propagating material of the variety:
>
> (a) produce or reproduce the material;
> (b) condition the material for the purpose of propagation;
> (c) offer the material for sale;
> (d) sell the material;
> (e) import the material;
> (f) export the material;
> (g) stock the material for the purposes described in paragraph (a), (b), (c), (d), (e) or (f).

Excepted by section 16 from these rights are acts carried out privately and for non-commercial purposes, for experimental purposes, or

for the purpose of breeding other plant varieties. Seed saved by a farmer from harvested material and treated for the purpose of sowing a crop on that farmer's own land is considered by section 17 not to be an infringement.

The section also provides for a particular taxon to be exempted by regulation. Section 18 provides that PBR are not infringed when propagating material is used as a food, food ingredient or fuel, or for any other purpose not leading to or involving the production or reproduction of propagating material. Finally, section 23 provides that PBR are exhausted following the sale of propagating material by a grantee unless there is a multiplication of the material after the sale.

Duration of plant breeders' rights

The general duration of PBR is provided by section 22 of the Act to be 25 years in the case of trees and vines and 20 years for any other variety. This duration commences from the date of grant of a PBR in the variety. Where a plant variety is declared under section 40 of the Act to be an 'essentially derived variety' from an initial variety, section 22 provides that the total duration of protection for the dependent or essentially derived variety can last for no longer than the duration of the protection of the initial variety.

Application for plant breeders' right

Eligible applicants

Section 24 of the Act states that a breeder can make application for a grant of PBR whether or not the breeder is an Australian citizen or resident in Australia, or the variety was bred in Australia. This section provides for two or more breeders to make a joint application.

The right of a breeder of a plant variety to apply for PBR under the Act is declared by section 25 to be personal property and capable of assignment and of transmission by will or by operation of law.

Ineligible applications

Section 14 of the Act provides that PBR are not to be granted in respect of varieties previously sold. The nature of transactions embraced by the concept of sale was considered by the Federal Court of Australia in Sun World International, Inc. v. Registrar, Plant Variety Rights (1997) 39 IPR 161; (1998) 42 IPR 321. That case concerned whether the sale of a nursery upon which Sugraone grape vines were growing constituted the sale of

the Sugraone variety. The trial judge, supported by the Full Federal Court, ruled this to have been a sale and that, therefore, the application to register the Sugraone variety was ineligible.

Form of application

The form of application for PBR is prescribed by section 26. It provides that an application must contain: (i) the name and address of the applicant; (ii) the name and address of an agent, if any, making the application on the applicant's behalf; (iii) if the applicant is the breeder of the variety, a statement to that effect; (iv) if the applicant is not the breeder of the variety, details of the applicant's right to make the application; (v) a brief description, with a photograph, if appropriate, of a plant of the variety sufficient to establish a prima facie case that the variety is distinct from other varieties of common knowledge; (vi) the name and any proposed synonym of the variety; (vii) particulars of the location at which and the manner by which the variety was bred, including particulars of the names by which the variety is known and sold in Australia and particulars of any PBR granted in Australia or in another country that is a signatory to the UPOV Convention; (viii) particulars of any application for, or grants of, rights of any kind in the variety in any other country; (ix) the name of an approved person who will verify the particulars of the application and who will supervise any test growing of the variety required under section 37 of the Act and who will verify a detailed description of the variety; and (x) such other particulars (if any) as are required by the approved form.

Application fee

An application fee may be prescribed under section 26(4) of the Act.

Acceptance or rejection

The Secretary of the Department of Agriculture (henceforth called 'the Secretary'), who is responsible for the administration of the Act, is required by section 30 of the Act to decide, as soon as practicable after an application is lodged, whether to accept or reject the application. Where the Secretary is satisfied that the application is prior in time to any other application and that it complies with the requirements of section 26 and establishes a prima facie case for treating the plant variety as distinct from other varieties, the application must be accepted. Upon acceptance the applicant must be notified that the application has been accepted and public notice of the acceptance of the application must also be given. Similar notification obligations apply where an application is rejected.

Variation of application

After an application for a PBR has been accepted, but before concluding the examination of that application, section 31 permits the Secretary to vary an application, subject to the payment of a prescribed fee. Section 32 requires the Secretary to notify the applicant for variation whether the request to vary has been accepted or rejected, setting out the reasons for the acceptance or rejection.

Withdrawal of application

An application is permitted by section 33 to be withdrawn by an applicant at any time. If this occurs after public acceptance of the application, the Secretary must, as soon as practicable, give public notice of the withdrawal.

Detailed description of the plant variety

As soon as practicable, but not later than 12 months after an application has been accepted, or within such further period granted by the Secretary, the applicant is required by section 34 to give the Secretary a detailed description of the plant variety to which the application relates. Failure to supply this description will result in the application being deemed to have been withdrawn. The detailed description must be in writing and in an approved form containing particulars of: (i) the characteristics that distinguish the variety from other plant varieties, the existence of which is a matter of common knowledge; (ii) any test growing carried out; (iii) any test growing outside Australia that tends to establish that the variety will, if grown in Australia, be distinct, uniform and stable; and (iv) such other particulars that may be prescribed. The Secretary is obliged by section 34 to give public notice of the detailed description as soon as practicable after it has been received.

Objection to application for plant breeders' rights

A person may object under section 35 to an application for PBR if they can establish that their commercial interests would be affected by the grant of PBR to the applicant and that the Secretary cannot be satisfied that the various substantive requirements of the Act have been met by an applicant. The objection must set out the particulars of the manner in which the person considers his or her commercial interests would be affected and the reasons why the person considers that the Secretary cannot be satisfied that the various substantive requirements of the Act have been met.

Inspection of application and objections

Section 36 of the Act provides that a person may, at any reasonable time, inspect an application for PBR in a plant variety, or an objection lodged in respect of that application. Upon the payment of a prescribed fee, section 36 provides for a copy of an application or an objection to an application to be provided.

Test growing of plant varieties

In the case of an application for PBR that has been accepted, or an objection to such an application, or a request for revocation of PBR, the Secretary may require a test growing, or further test growing, of the variety. In such a case, section 37 requires notice to be provided to all relevant persons. The notice, in addition to telling the applicant, objector or grantee of the Secretary's decision, must specify the purpose of the test growing and may require the person to supply the Secretary with sufficient plants or propagating material and with any necessary information to permit the Secretary to arrange a test growing, or to make arrangements for an approved person to supervise the test growing and to be supplied with plants or propagating material. The expense of a test growing must be borne by the applicant, objector or person requesting revocation of the PBR. Section 38 provides for a test growing outside Australia of a plant variety that was bred outside Australia.

Provisional protection

Where an application for a PBR is accepted, the applicant is taken to be the grantee of that right from the date that the application is received until the application is disposed of. During this period of provisional protection, the applicant is prevented by section 39 from commencing any infringement action in respect of the PBR, until such time as the application is finally resolved in the applicant's favour.

Declarations of essential derivation

Where a person is the grantee of a PBR in a particular plant variety (the initial variety) and another person is the grantee of, or has applied for, PBR in another variety (the second variety), the grantee of PBR in the initial variety may seek a declaration from the Secretary under section 40 that the second variety is an essentially derived variety of the initial variety. A plant variety is defined in section 4 of the Act to be an essentially derived variety of another plant variety if: (i) it is predominantly derived

from the other plant variety; (ii) it retains the essential characteristics that result from the genotype or combination of genotypes of that other variety; and (iii) it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.

The application for essential derivation must be in an approved form and contain such information relevant to establishing a prima facie case of essential derivation. If the Secretary is satisfied or not satisfied as the case may be that a prima facie case has or has not been established, the applicant and the grantee of PBR in the second variety must be informed and provided an opportunity to rebut the prima facie case. Section 41 permits the Secretary to order a test growing in order to rebut a prima facie case of essential derivation. A similar test growing regime is provided for by the section to that contained in section 37.

Grant of plant breeders' rights

Registrable plant varieties

Section 42 provides that PBR must not be granted to any variety of plant in a taxon declared by regulation to be one to which the Act does not apply. However, it is not envisaged that this provision will be implemented, since the 1991 UPOV Convention requires that all plant varieties be eligible for PBR. A plant variety is considered to be registrable, pursuant to section 43, if the variety has a breeder, is distinct, uniform, stable and has not been or has only recently been exploited. For the purposes of this section, a plant variety is distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge. It is uniform if, subject to the variation that may be expected from the particular features of its propagation, it is uniform in its relevant characteristics on propagation. A plant variety is stable if its relevant characteristics remain unchanged after repeated propagation. A plant variety is taken under section 43 not to have been exploited if it or propagating material has not been sold to another person by or with the consent of the breeder. For the purposes of this section, a plant variety is taken to have been only recently exploited if, at the date of lodging the application for the PBR in the variety, propagating or harvesting material has not been sold to another person by, or with the consent of, the breeder, in Australia, more than 1 year from that date. In the case of exploitation in other UPOV signatory states, the sale should not have been more than 6 years before that date in the case of trees or vines, or more than 4 years before that date in any other case. A plant variety is treated by section 43(8) as a variety of common knowledge where, in addition to any other reason, an application for PBR in the variety has been lodged in a UPOV contracting state.

Grant of plant breeders' rights

Where an application for PBR in a plant variety is accepted, section 44(1) provides that following examination of the application the Secretary must grant the right to the applicant where the Secretary is satisfied that: (i) there is such a variety; (ii) the variety is registrable within section 43; (iii) the applicant is entitled to make the application; (iv) the grant of that right is not prohibited by the Act; (v) the right has not been granted to another person; (vi) the name of the variety complies with section 27; (vii) propagating material of the variety has been deposited for storage, at the expense of the applicant, in a genetic resource centre approved by the Secretary; (viii) in the case of a species indigenous to Australia, a satisfactory specimen plant has been supplied to a prescribed herbarium; and (ix) all fees have been paid.

PBR is granted by the issue of a certificate in approved form. Section 45 provides that only one grant of PBR may be made under the Act in relation to a plant variety, irrespective of the number of owners of that variety, or whether that variety is an initial variety or a derived variety.

Effect of grant of plant breeders' rights

If a person is granted PBR in a plant variety, section 48 provides for the grantee the right to take precedence over any other person who was entitled to make an application for the right in the variety. Such person is not prevented, however, from applying for a revocation of rights under section 50, or from seeking administrative review of the Secretary's actions in relation to the grant of PBR, or from requesting the Secretary to make a declaration under section 39 that the right that was granted was essentially derived from another plant variety. Where it transpires that another person was entitled in law or equity to an assignment of the right to make an application for the PBR, that person is entitled to an assignment of the PBR.

Grant of plant breeders' rights subject to conditions

Section 49 envisages that where the Minister for Agriculture considers it appropriate a PBR may be granted subject to conditions. In this regard, the Minister would probably take the advice of the Plant Breeders' Rights Advisory Committee, established under section 63 of the Act.

Revocation

Section 50 provides for the revocation of PBR or a declaration that a plant variety is essentially derived from another plant variety if the Secretary becomes satisfied that facts existed that, if known before the grant of the

right or the making of the declaration, would have resulted in the refusal to grant the right or make the declaration. Revocation may also result from a failure to pay prescribed fees. Within 7 days of the decision to revoke, the grantee or transferee of a PBR must be provided with particulars of the grounds of proposed revocation. That person then has 30 days to provide a written statement to the Secretary. Applications for revocation may be made by a person whose interests are affected by the grant of PBR in a plant variety or by a declaration of essential derivation. In the event of revocation or surrender of a PBR, section 51 provides for the particulars of revocation or surrender to be entered in the Register and to be published.

Compulsory licensing

Section 19 of the Act requires the grantee of PBR in a plant variety to take all reasonable steps to ensure reasonable public access to that plant variety. This requirement is taken to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet demand. For the purpose of ensuring reasonable public access, section 19(3) permits the Secretary to license an appropriate person to sell propagating material of plants of that variety, or to produce propagating material of plants of that variety for sale 'during such period as the Secretary considers appropriate and on such terms and conditions (including the provision of reasonable remuneration to the grantee) as the Secretary considers would be granted by the grantee in the normal course of business'. An exception to the grant of a compulsory licence applies in the case of a plant variety that has 'no direct use as a consumer product' (section 19(11)).

A person may make a written request to the Secretary under the section for the grant of a licence where a person considers that a grantee is failing to ensure reasonable public access to a plant variety and that failure affects that person's interests. The request must set out particulars of the alleged failure and of the effect upon that person's interests. The Secretary is then required by section 19(6) to provide the grantee an opportunity within 30 days to satisfy him that the grantee is providing reasonable public access to a plant variety, or that he will comply within a reasonable time. Where the Secretary decides to grant a licence under section 19, a public notice must be issued identifying the variety, detailing the particulars of the licence that is proposed to be granted and an invitation to persons to apply for a licence (section 19(8)). The Secretary is required to consider all applications and, at least 1 month prior to granting a licence, must publicly notify the name of the proposed licensee, as well as notifying each of the applicants (section 19(9)).

Infringement of plant breeders' rights

Infringing acts

Generally speaking, PBR in a plant variety is infringed by an unauthorized person: (i) doing one of the acts that are comprised in the PBR defined in section 11 of the Act; (ii) claiming the right to do one of those acts; and (iii) using the name of a registered variety in relation to another plant or another plant variety (section 53(1)). An action for infringement is brought in the Federal Court of Australia.

Defences

An infringement will not occur where the act complained of is exempted from the operation of section 11, e.g. by sections 16–19 and 23. A defendant in an action for infringement may counterclaim for revocation of that right on the ground that the variety was not a new plant variety, or that facts exist that would have resulted in the refusal of the grant of that right. Under section 55, a person who proposes to perform an act described in section 11 may, by an action against a grantee of PBR in a plant variety, apply for a declaration that the performance of that act would not constitute an infringement of that right.

Remedies

The Court in an infringement action may grant an injunction subject to any terms that the Court thinks fit and, at the option of the plaintiff, either damages or an account of profits (section 56). Where a person satisfies the Court that at the time of the infringement he/she was not aware of and had no reasonable grounds for suspecting the existence of that right, it may refuse to award damages or order an account of profits. This exoneration for innocent infringements is not available where propagating material of the plant variety, labelled so as to indicate that the PBR is held in Australia, has been 'sold to a substantial extent before the date of the infringement' (section 57(2)).

Administration

Registrar of Plant Breeders' Rights

Section 58 of the Act provides for the establishment of the Office of the Registrar of Plant Breeders' Rights, which is responsible for the general administration of the Act and for the maintenance of the Register of Plant Varieties.

Plant Varieties Journal

Under section 68 of the Act, the Secretary is required to issue a Plant Varieties Journal in which all public notices are to be published.

Genetic resource centres and herbaria

The Act in section 70 provides for the nomination of genetic resource centres for the storage and maintenance of germplasm material. An organization with the facilities for storing plant material may be declared a herbarium under section 71 of the Act.

Plant Breeders' Rights Advisory Committee

The Plant Breeders' Rights Advisory Committee is established by section 53 of the Act with the role of advising the Registrar on technical matters arising under the Act. Additionally, the Advisory Committee is required to advise the Minister on any regulations exempting taxes from the operation of the Act and any extension of the term of protection under section 22 of the Act.

Transitional

Plant variety rights granted under the Plant Variety Rights Act 1987 are preserved as PBR under section 82 of the Act and under section 80. The Register of Plant Varieties under the old Act is incorporated into the Register established under section 58 of the Act.

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China

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Introduction

No other country has experienced such an unprecedented economic growth rate as the People's Republic of China (PRC) since the early 1990s. Paramount Leader Deng Xiao Ping's economic reforms changed the face of the PRC, bringing great opportunities for foreign investors and enterprising Chinese. Currently, one of the greatest concerns facing foreign investors is protection of their intellectual property rights (IPR). This chapter intends to give an easy to follow yet comprehensive guide to the laws and issues relating to intellectual property (IP) protection in the PRC.

On a world scale, the PRC has a relatively advanced framework of laws governing IP. It is a member of most international treaties governing IP, a member of the World Intellectual Property Organization (WIPO), a United Nations (UN) Agency and now also a member of the World Trade Organization (WTO). As a member of the WTO, China needs to implement the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS).

Current Status of Intellectual Property Laws

Administrative framework

The PRC has set up a network of agencies and offices to administer IP at both national and local levels. These offices and agencies report directly to the State Administration for Industry and Commerce (SAIC), a gov-

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ernment ministry under the State Council. Other branches of the government that participate in IP enforcement are the customs authorities, the Public Security Bureau, the Procuratorate, the Press and Publications Bureau and the Ministry of Culture.

For trademark and service mark matters, two offices under the SAIC administer registration and disputes: the Trademark Office and the Trademark Review and Adjudication Board. Passing off of registered trademarks, which is considered as an act of unfair competition, is dealt with by the Fair Trade Bureau of the SAIC. Administrations for Industry and Commerce (AICs) are established at the local levels in the PRC (provincial, city, county) and can be requested to conduct raid actions, after they have been presented with proof of the IPR and the infringing activities. The powers of the AICs are clearly specified in the PRC IP laws, giving the authorities the right to enter premises, seize accounts and records, seal and destroy goods and impose fines. The AICs are also empowered to award compensation after considering the severity of infringement.

For copyright matters, the National Copyright Administration (NCA) is in charge of the nationwide administration of copyrights, including copyrights belonging to foreigners. Like the AIC offices, there are also copyright offices at local levels in the PRC (usually the provincial and city levels). The PRC Copyright Law requires foreign complainants to file their complaints with the NCA at the central level in Beijing, regardless of where the infringement has taken place. For patent matters, the Patent Office is the government agency that handles legal and administrative matters.

The judiciary has established specialized IP courts to adjudicate IP cases. The judges who serve in these courts have been trained to handle IP cases. If an infringed party wishes to take action, in compliance with trademark, copyright and patent laws, the infringed party can take their case through the courts or through an administrative agency. In practice, administrative recourse has proved to be more effective because of the relative expertise of officials and their ability to conduct raid actions with little warning. Court proceedings are time-consuming and generally offer very little in the way of compensation. Additionally, a new Working Conference on Intellectual Property Rights was established as part of the 1995 China–US Agreement on Intellectual Property Rights.

Legislative framework

Trademarks and service marks

The laws governing trademarks and service marks are: the Trademark Law of the People's Republic of China (the 'Trademark Law'), which came into force on 1 March 1983 and was revised on 1 July 1993 and then again on 27 October 2001 (effective from 1 December 2001), and the

Implementing Regulations of the Trademark Law of the People's Republic of China (the 'Trademark Implementing Regulations'), which came into force on 15 September 2002.

The revised Trademark Law provides for judicial review of administrative cases, including application appeals, oppositions and cancellations. It also allows three-dimensional marks and marks that have acquired distinctiveness through use to be registered. The revised Trademark Law has also changed the methods of enforcement. Preliminary injunctions are now available and a judicial interpretation was issued on 22 January 2002 by the Supreme People's Court setting out the details. Relevant authorities have been given more enforcement and investigative power to stop infringers' conduct and to seize and/or destroy counterfeits. Statutory damages up to RMB500,000 and 'reasonable' attorney or investigation costs may now also be recovered. Under the revised Trademark Law, the AICs no longer have the right to award compensation to the party whose rights have been infringed. Instead, the AICs are encouraged to assist parties to reach settlements through mediation and are required to transfer cases for criminal investigation to the Public Security Bureau based on suspicion of crime.

The new Trademark Implementing Regulations significantly increase the maximum fines that may be imposed against trademark infringers, provide more explicit protection for owners of marks that are deemed to be 'well-known', and streamline the handling of various procedures at the registry. Applicants are now allowed to amend and assign pending applications. Joint trademark applications are possible. The Trademark Office has been given the power to grant or refuse preliminary approval for the registration of marks covering only a portion of the designated goods or services. Under the Trademark Implementing Regulations, AICs are empowered to impose fines up to three times the infringer's 'illegal business amount'. However, if it is impossible to ascertain the 'illegal business amount', a discretionary fine up to RMB100,000 can be imposed by the AICs.

Marks that possess a distinctive character may be registered. However, marks that are generic or descriptive of the quality, ingredients, functions or other characteristics of the products for which the trademark is to be used may not be registered. Once a trademark is registered, it is valid for 10 years and may be renewed for consecutive periods of 10 years. The PRC has adopted the 'first-to-file' rule for obtaining trademark rights, regardless of prior use. This means that the first applicant to file an application for registration of a mark will pre-empt all later applicants. There is, however, an exception to the rule. Under the Paris Convention for the Protection of Industrial Property, 'well-known' marks can be protected even if they have not been registered. Previously, for recognition of a well-known mark, Chinese authorities would generally have required proof that the mark enjoyed a leading market position in the original country of manufacture, had a substantial degree of name recognition in

the international market and had achieved a substantial degree of fame within the PRC. The problem with these criteria was their vagueness. This was remedied by the Revised Trademark Law, which provides specific factors for determining whether a mark is 'well-known'. Now, foreign marks need not be famous in China nor registered in China to be considered 'well-known'. The new Trademark Implementing Regulations confirm that trademark owners pursuing oppositions and cancellations may seek formal recognition of their marks as 'well-known', thereby aiding in attempts to block others from registering similar marks covering dissimilar goods or services. The Trademark Implementing Regulations make it clear that determinations on well-known status will be made on a case-by-case basis. In any event, it remains the case that trademark protection in the PRC is best secured through registration. In addition, in accordance with the Paris Convention, nationals of other member nations may claim priority use of trademarks within 6 months of the first filing.

It used to be the case that registration in the PRC was advisable even for companies that had not entered the Chinese market. PRC trademark registrations could be maintained by advertising the marks once every 3 years in an approved PRC publication. Thus, companies that had not yet sold products or licensed trademarks in China due to investment restrictions could obtain trademark registrations and maintain their rights in anticipation of future use. However, there are now indications that the Trademark Office has adopted more stringent policies and that some bona fide commercial purpose is required for such advertising. The exact standards for satisfying use requirements are in flux.

In addition, China has taken steps to bring its trademark protection laws in line with international standards. In 1988, the PRC changed their classification of goods to comply with the International Classification of Goods and Services, used by most trademark registries throughout the world. In October 1989, the PRC entered into the Madrid Agreement for the International Registration of Marks. The Madrid Agreement permits owners of international registrations to obtain trademark and service mark registrations in all other Madrid Union countries upon payment of a modest fee. An international registration is obtained by filing a trademark or service mark application in a country in which the applicant has a 'real and effective industrial commercial establishment'.

Copyright

The main laws governing copyrights in the PRC include: (i) the Copyright Law of the People's Republic of China (the 'Copyright Law'), which was first issued in 1991 and was revised to take effect from 27 October 2001; (ii) the Implementing Regulations of the Copyright Law of the People's Republic of China (the 'Copyright Implementing

Regulations'), effective from 15 September 2002; (iii) the Regulations for the Implementation of International Copyright Treaties, effective from 30 September 1992; and (iv) the Regulations for the Protection of Computer Software (the 'Software Regulations'), which was first issued in 1991 and was revised with effect from 1 January 2002.

International agreements

The PRC extends protection to foreign works upon 'first publication' of a work in China, or within 30 days of publication elsewhere. As a result of the Memorandum of Understanding signed by the USA and China on 17 January 1992, all US works not in the public domain are now protected while works of residents of other member countries may be protected under relevant international conventions, for example, the Bern Convention for the Protection of Literary and Artistic Works (Bern Convention) and the Universal Copyright Convention.

Works and term of protection

Under the Copyright Law of the PRC, the following may be protected: literary works; oral works; musical, dramatic and choreographic/acrobatic works; works of fine art; architectural works; photographic works; cinematographic works, works created by a process analogous to cinematography (for example, television and video works); product engineering designs and their explanations; maps and schematic drawings; and computer software.

The term of protection is generally the life of the author plus 50 years. In cases of copyrights originally vested in a legal person, and copyrights in cinematographic, television and photographic works and in video and sound recordings, the duration of protection is 50 years from the date of first publication.

The revised Copyright Law

The revised Copyright Law provides for an increased scope of protection. There is explicit protection of the following rights: rental rights in films (cinematographic works) and particular software; public performance rights, including performance of films; rights to distribute works through the Internet; original compilations of works; and rights for digital works. In relation to digital works, a Supreme Court Interpretation was issued in November 2001, clarifying an Internet service provider (ISP)/Internet content provider (ICP)'s responsibility. Consistent with China's commitments under the WTO, the Copyright Implementing Regulations explicitly recognize protection of performance and sound recordings produced or distributed by foreigners and stateless persons.

Enforcement of copyright has also been strengthened through civil and administrative measures. Preliminary injunctions are available, and a judicial interpretation by the Supreme Court in relation to such measures is expected to be issued. Statutory damages of up to RMB500,000 are available in cases where the plaintiff's damages or the infringer's profits cannot be determined. In addition, 'reasonable' attorney or investigation costs are recoverable. The scope of administrative sanctions has also been widened. The NCA and local copyright bureaux are authorized to issue administrative injunctions, confiscate illegal income of infringers, confiscate and destroy infringing copies, issue fines and confiscate materials, tools, facilities, etc. primarily used for the production of infringing copies.

The new Copyright Implementing Regulations permit the imposition of administrative fines against infringers up to three times the illegal turnover of an infringer, provided it is determined that infringement has caused 'harm to social and public interests'. If it is difficult to determine the amount of illegal turnover, a fine of up to RMB100,000 may be imposed.

The revised Copyright Law also specifically permits the full or partial assignment of economic rights in the copyright subject matter. It removes an earlier restriction that copyright licences should be limited to 10 years.

The revised Computer Software Protection Regulations

Copyright protection for computer software in the PRC has until recently been governed by the general provisions in the Copyright Law together with the *Regulations for the Protection of Computer Software*, which were originally issued by the State Council in 1991 ('Software Regulations'). The State Council recently amended these regulations, and the revisions entered into effect on 1 January 2002.

The amendment of the Software Regulations follows the enactment in October 2001 of changes to the PRC Copyright Law, many of which were introduced to ensure China's compliance with the requirements of the TRIPS Agreement of the WTO.

The revised Software Regulations eliminated the 10-year licence limit that previously existed. Protection is now accorded to new types of software use, including rental rights and the right to authorize 'broadcast over information networks' (e.g. the Internet). This follows the issuance in December 2000 of a Supreme Court interpretation on civil liability against network pirates. In addition, anti-circumvention measures are prohibited. The 25-year limitation on protection under the 1991 regulations has been removed, and the period of protection is now 50 years from publication.

The revised Software Regulations also eliminate the compulsory licensing of works owned by State-owned companies. They still permit

registration of software copyright for the purpose of providing prima facie evidence of ownership and validity of software. This registration is voluntary, and is not a requirement for enforcement.

The revised Software Regulations permit rights holders to file complaints with either civil courts or administrative enforcement authorities. Under the prior Implementing Rules, foreigners were required to file complaints with the NCA in Beijing, whereas local copyright owners were empowered to file complaints directly with local copyright bureaux, which operate under NCA's supervision. In practice, NCA and local copyright bureaux have removed this restriction on complaints by foreigners. It is likely that this practice will be codified in the future Implementing Rules to ensure compliance with the principle of 'national treatment' under the WTO.

Meanwhile, however, the revised Software Regulations impose new restrictions on the filing of administrative complaints by both local and foreign copyright owners. Administrative enforcement is now excluded for cases involving the unauthorized 'publication' of works (i.e. their first disclosure to the public) or their 'revision, translation or annotation'.

Furthermore, administrative enforcement is now restricted in cases involving reproducers or distributors of infringing software to cases where the infringements might harm the public interest. The revised regulations do not attempt to define how the public interest will be determined for these purposes, and further clarification from NCA and local copyright bureaux will therefore be required in the coming months.

The revised regulations suggest that complaints filed through administrative authorities should be accepted in relation to cases involving the following:

- public rental or dissemination of software through information networks (the Internet);
- circumvention or sabotage of technological measures used by software copyright owners; and
- the removal or alteration of electronic rights management information incorporated into works to facilitate copyright protection.

The new regulations also give administrative authorities more explicit powers to deal with infringements than under the old regulations, including the powers to issue injunctions, confiscate the illegal income of infringers, confiscate or destroy infringing products and impose fines. In 'serious cases', administrative authorities may also confiscate materials, tools and facilities primarily used for the production of infringing copies.

The amount of administrative fines was not specified in the previous Software Regulations, and fines were instead set out in separate implementing rules. However, the revised regulation now specifies that a max-

imum fine of RMB100 (about US$11) for each infringing item, or alternatively five times 'the value of the goods', may be imposed in cases involving unauthorized copying of all or a portion of the software, as well as for unauthorized distribution, rental or transmission via information networks (the Internet). The definition of 'the value of the goods' is not set out in the regulations and does not specify whether reference should be made to the rights owner's prices or the infringer's prices, or the retail, wholesale or some other valuation method.

The regulations indicate that fines up to RMB50,000 (US$6000) may be imposed for wilful evasion or destruction anti-circumvention measures. The decisions of administrative enforcement authorities may be appealed to Chinese courts. Under China's Civil Code, the civil courts have the power to impose the above fines against infringers, even where administrative complaints have not been filed.

Domain name

The top-level domain name officially registered by China with InterNIC is 'CN'. Second-level domain names are divided into so-called 'category domain names' and 'administrative division domain names'. The category domain names are: 'AC' for scientific research institutions; 'COM' for industrial, commercial and financial enterprises; 'EDU' for educational institutions; 'GOV' for government authorities; 'NET' for information centres and operations centres connected to networks; and 'ORG' for non-profit organizations. Roman-letter and Chinese-language domain names are both registrable.

The Ministry of Information Industry (MII) is responsible for policy and regulations, the system for top-level domain name 'CN' and Chinese-language domain names, administration of the China Internet Network Information Center (CNNIC), administration of domain name root servers within China and international coordination for domain names.

CNNIC, on the other hand, is responsible for operation and administration of the domain name system, maintenance of the database and authorizing the Registrars to provide the domain name registration services. The Registry is also responsible for making rules and monitoring the services offered by the Registrars. CNNIC's database of 'CN' domain names is accessible by the public via searches at: www.cnnic.net.cn

Domain names can now be registered in the names of entities located outside China, and the primary and secondary servers for such names need not be located in China either.

Disputes over roman-letter and Chinese-language domain names can be handled through non-judicial dispute resolution similar to the Internet Corporation for Assigned Names and Numbers (ICANN) Uniform Domain Name Dispute Resolution Policy (UDRP). Disputes

under the new Dispute Resolution Policy (DRP) can be filed with the China International Economic and Trade Arbitration Commission (CIETAC) and the Hong Kong International Arbitration Centre (HKIAC).

DRP proceedings should be concluded within 2 months. Proceedings will normally be handled through written submission, although if the panel believes it necessary, it may hold an open hearing to discuss the case. Hearings may also be held upon the request of one of the parties, subject to its payment of additional fees. During the course of DRP proceedings, the holders of domain names may not transfer their names to third parties.

The remedies imposed by DRP panels are limited to orders to transfer domain names, and panels are authorized to order the payment of compensation or any other remedies.

The parties may file civil actions at any time during or after DRP proceedings. However, if the DRP panel orders the transfer of a name and the respondent fails to file a civil action within 10 days of the order, the name will be transferred to the petitioner by CNNIC.

The official fees for DRP complaints will depend on the number of arbitrators selected. The fee payable to CIETAC for a panel consisting of only one arbitrator is US$360, while the fee for a panel of three arbitrators is US$720.

Licensing and compulsory licensing of copyrights

The right of a copyright owner to grant a licence over the copyright work and to receive remuneration for the granting of the licence is governed by an agreement between the parties of the relevant provisions of the revised Copyright Law. The old Article 26 of the Copyright Law that limited the term of copyright licences to 10 years has since been repealed. Article 22 of the revised Copyright Law permits use of a published work 'to a reasonable extent' by a state entity where such use is for the purpose of carrying out official duties. Articles 39 and 42 of the revised Copyright Law permit the use of copyright works by any user who pays the owner remuneration.

Regulations for the implementation of international copyright treaties

Under the regulations, foreign works of applied art are protected for 25 years from their creation. Foreign computer programs are also protected as literary works that do not require registration and are protected for 50 years from the end of the year of first publication. Also included in the regulations is the protection of foreign works that are created by compiling non-protectable materials that possess originality. There is also elimination of certain limitations imposed by the Copyright Law on the copyright owner's rights to comply with the Bern Convention.

Patents

The Patent Law of the People's Republic of China (the 'Patent Law') and its implementing regulations came into effect in April 1985. It was first amended in 1992, in part to address WTO concerns. The most recent amendments to the Patent Law and the Detailed Implementing Rules for the Patent Law of the People's Republic of China came into force on 1 July 2001.

Effective from 1 January 1994, China became a member of the Patent Cooperation Treaty (PCT). Consequently the PRC Patent Office can now receive international applications filed by applicants in any contracting states of the PCT.

The Patent Law, like the Trademark Law, adopts a first-to-file system. Accordingly, the first inventor to file an application for an invention has the right to patents awarded with respect to the invention. Pursuant to the Paris Convention, however, if a patent application for an invention or utility model is first filed in another Convention-member country within 12 months before the filing date in the PRC, the prior filing date will be regarded as the priority date in the PRC. The relevant period is 6 months in the case of design patent applications.

The Revised Patent Law gives stronger protection with respect to vendors of infringing items. The scope of the Patent Law has been widened to include the right to prohibit unauthorized 'offering for sale'. Provisional measures such as preliminary injunctions are now available, and compulsory licensing conditions have been refined. In addition, judicial review of Patent Re-examination Board decisions are possible. The revocation procedure has been removed, and only invalidation proceedings are now present under the new law. Compensation is based on the infringer's profits, the patent owner's damages or a reasonable multiple of the patent licensing fee.

Administrative protection of agrochemical products

Regulations for the Administrative Protection of Agrochemical Products were promulgated by the Ministry of Chemical Industry on 1 January 1993. This legislation provides so-called 'pipeline protection' for agrochemical products patented between 1 January 1986 and 1 January 1993 in certain foreign countries and under stipulated conditions.

Pipeline protection is available to such products that are owned by individuals and enterprises from countries that have entered into bilateral agreements with the PRC (at present, these countries include the USA, Japan, Switzerland and members of the European Union).

The procedure for applying for pipeline protection is set out in regulations issued by the Ministry of Chemical Industry (MCI). The regulation and implementing rules define agrochemical products as chemically

synthesized agricultural chemicals, including herbicides, insecticides, fungicides, rodenticides and plant growth regulators produced by chemical synthesis. Enterprises, organizations and individuals in countries that have concluded a treaty or agreement with the PRC concerning administrative protection of agrochemical products may apply to the MCI for administrative protection.

To qualify for administrative protection, agrochemical products must satisfy the following criteria.

1. They must not have been eligible for protection under the PRC Patent Law prior to 1 January 1993.
2. They must have enjoyed exclusive rights through product patents granted in the applicant's home country between 1 January 1986 and 1 January 1993.
3. They must not have been marketed in the PRC prior to 1 January 1993.

Applications for administrative protection of agrochemical products must be processed through the China Hua Ka Pharmaceutical Intellectual Property Consultancy Centre. Each application may cover only one agrochemical product. Applications must be submitted in written form without alterations and include the following in both Chinese and the official language of the applicant's country:

- the name, formula or prescription, and method of application of the product;
- a copy of the document issued in the applicant's country proving that the applicant has the exclusive rights to the product;
- a copy of the contract for the manufacture or sale of the product in China formally entered into between the applicant and a Chinese legal person; and
- a Power of Attorney in favour of the agent.

The term of administrative protection is for 7 years and 6 months from the date on which the certificate of administrative protection is issued. Foreign owners of such exclusive rights must pay an annual fee. Administrative protection may be terminated early if the exclusive rights to the product in the owner's country become void, or if the owner does not apply to the State Council's administrative department of agriculture for permission to manufacture or sell its product.

If a protected agrochemical product is manufactured or sold without a licence from the owner of the exclusive rights, the owner may request the MCI to stop such activity and may institute an action in a People's Court for financial compensation.

Unfair competition and passing off

China's Unfair Competition Law was promulgated by the State Council on 2 September 1993. It provides some protection for unregistered trade-

marks, packaging, design and get-up. It also prohibits acts of unfair competition by monopolies or cartels to control prices in the market. Protection is also given to confidential information and business/trade secrets. The Unfair Competition Law prohibits business operators from engaging in the following acts of unfair competition:

- passing off the registered trademark of another party;
- unauthorized use of the name, packaging or design peculiar to well-known packaging;
- unauthorized use of the enterprise name or personal name of another party;
- use of certification marks, marks of fame, or marks of excellence that are counterfeit or used without authorization; and
- falsification of the place of origin or making of misleading and false statements as to the quality of the merchandise.

The Unfair Competition Law also prohibits the infringement of 'business secrets', defined as technical and business information that is 'private' and 'can bring economic benefits' to the rightful party and for which the rightful party has adopted measures to maintain its confidentiality. If a claimant wishes to take action against an infringer, the SAIC is empowered to impose fines and to order and supervize the return by the infringer of blueprints/drawings and software or other relevant materials.

The World Trade Organization and China

In 1947, the Nationalist government of China was one of the signatory nations to the General Agreement on Tariffs and Trade (GATT). After the Communist victory, the newly established PRC withdrew its membership in 1950. Since 1986, the PRC has been trying to accede to the WTO, finally succeeding on 11 December 2001.

Accession to the WTO also entails PRC's compliance with the WTO TRIPS Agreement. The TRIPS Agreement provides fundamental WTO principles of national treatment and most-favoured-nation treatment for all protected categories of rights; minimum standards of protection for the most important forms of IP; standards for enforcement of those forms of IP; a binding, enforceable dispute settlement mechanism to resolve disputes regarding WTO Members' compliance with the established standards; and general rules to ensure that procedures for acquiring and maintaining IPR are not unduly time-consuming or costly. The main bar to the effective implementation of the TRIPS Agreement in the PRC will not be a lack of appropriate laws, but rather endemic weaknesses in the IPR enforcement regime – failure to enforce court decisions and insufficient funding for IP enforcement bodies. In the long term, PRC's accession to the WTO means one less impediment to foreign investment.

Changes in Legislation

There have been significant changes to the major IP laws in the PRC due to increased international pressure. The US–China IP Agreement of 1995 and 1996 focused heavily on copyright infringement. Together with its accession to the WTO, China has called for an increased enforcement campaign against audio-visual and computer software pirates, implementing new and stricter regulations of audio-visual production factories.

Customs officials have been granted greater powers to monitor exported products and imported machinery, particularly goods that can be used to manufacture audio-visual products. To monitor and trace audio-visual products, a title verification system for CD-ROMs, compact discs and laser discs has been implemented. By law, audio-visual products must also carry a unique identification code imprinted on the product surface.

Technology Transfer

The laws governing technology transfer have changed considerably since China opened its doors to foreign investment. The main piece of legislation is the Regulations on the Administration of Technology Imports and Exports of the PRC (the 'Regulations'), promulgated on 18 December 2001 and effective from 1 January 2002. The Regulations replaced the Regulations on the Administration of Technology Import Contracts and the Detailed Rules for the Implementation of the Regulations on the Administration of Technology Import Contracts.

Technology Import and Export is defined under the Regulations as the transfer of technology by way of trade, investment, or economic cooperation in technology from within the PRC to outside the PRC and vice versa. This includes the transfer of the following: patents; the right to apply for patents; patent implementation licences; technological services; technological secrets and other means of technological transfer.

The Regulations generally provide for the free import and export of technology subject to the following: (i) Technology that falls within the prohibited category in Article 16 of the PRC Foreign Trade Law cannot be imported or exported. (ii) Technology that falls within the restricted category in Article 16 of the PRC Foreign Trade Law can only be imported or exported with a licence granted by the Ministry of Foreign Trade and Economic Cooperation (MOFTEC) or its local delegates. MOFTEC is responsible for the national management of technology import and export. MOFTEC's local delegates are responsible for the local management of technology import and export. (iii) Technology that falls within the permitted category is managed by contract registration. The procedures for the application and approval of licences and for contract registration are stipulated in the Regulations.

When establishing a Foreign Investment Enterprise (FIE) that puts up technology as its investment, the import of such technology is governed by the examination, approval and registration procedures laid down for the establishment of FIEs.

Breach of the Regulations can result in penalties under the Criminal Law and the Customs Law. Licences may also be revoked or suspended if fraud or illegal means were used in obtaining the same. The Regulations further provide that MOFTEC, its local delegates and their staff have a duty to keep commercial secrets confidential. Failure to do so may result in criminal or administrative sanctions.

Conclusion

The IP laws of the PRC, and the courts and administrative agencies that enforce them, provide a strong framework for the protection of IP in the PRC. The greatest challenge facing the PRC is effective and consistent enforcement of this framework. Local protectionism and lack of trained personnel contribute to the weaknesses in enforcing IP protection. The PRC needs to continue on its course of training enforcement personnel and judges, so that it can develop into a country where both foreign investors and local interests can be confident that their IPR will be fully and effectively protected. A safer country for IP holders will attract increased foreign investment, particularly in more advanced technologies, which would in turn assist China in its path towards modernization and long-term economic growth.

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Issues on Intellectual Property Rights Associated with AgroBiotechnology in Japan

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National Perspective

Current status of intellectual property laws

General legal status

As Japan is known as a constitutional state, intellectual property (IP) laws are well established in conventional matters (Table 12.1; Anon., 1996a). Japanese patent IP principles are based on the first-to-file system, which is different from the first-to-invent system in the USA. The overall patent examination standards were revised in 1993 towards international harmonization and emphasize: (i) simplification of standards by integration of previous rules, which were rather vague; (ii) enforcement of inventors' and owners' rights by allowing extension of covered subjects/categories in a patent application; and (iii) addition of standards in (a) computer software and (b) biotechnology. Particular note should be made of the following: (i) the examination process is waived for the utility model as of 1 January 1994; (ii) copyrights principally belong to an organization, even when an individual employee creates publication/presentation material as part of his/her duty for the organization; (iii) industrial property rights can be owned by individual employees, even when the invention was made as part of the job for the

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Table 12.1. Intellectual property rights in Japan and their brief descriptions.

Category	Type of rights	Law	Subject protected	Key points for granting protection	Protected Period
Industrial property rights	Patent	Patent Law	Invention	Availability for industry innovativeness, improvement	20 years after application
	Utility model	Utility Model Law	Idea/device	Availability for industry innovativeness, improvement	6 years after application
	Registered design	Registered Design Law	Design	Availability for industry innovativeness, creativity	15 years after registration
	Registered trademarks	Registered Trademarks Law	Trademark/brand/ service mark	Distinguishable from others	10 years after registration, renewable
Copyrights	Copyright property	Copyright Law	Publications	Originality	50 years after publication
	Neighbouring right	Copyright Law	All rights associated with publications	Originality	50 years after publication or 50 years after death of author/performer
	Moral right	Copyright Law	All rights associated with author/performer	Originality	No fixed term
Others	Trade secret	Unfair Competition Prevention Law	Industrial rights	–	Conditional with associated right
	Protection of allotment of semiconductor circuit	Law for Protection of Allotment of Semiconductor Circuit	Idea/device on allotment of semiconductor circuit	Originality	10 years after registration
	Crop variety protection	Seed and Seedling Law	Plant varieties	Originality, improvement	15 years after registration 18 years for perennials

employer, however, the employer can use the industrial rights without rewards back to the employee; (iv) an online application has been available since December 1990; and (v) commercial insurance premiums have been available for covering legal actions against infringement since September 1994.

The Japanese Patent and Trademark Office issued amendments on 26 April 2002 under the title 'Review of Patent Law and Trademark Law' (www.jpo.go.jp/index.htm). A summary of the areas covered by these amendments is as follows:

1. Reinforcement of patent protection for information-based property such as software and enhancement of network transactions.
2. Expansion of provisions for indirect infringement of patent law.
3. Reinforcing protection of trust for trademarks used in an Internet business.
4. Reduction of applicant burden and promotion of speedy and efficient examination.

The laws listed in Table 12.1 are, in general, internationally harmonized as Japan has participated in the World Intellectual Property Organization (WIPO) since 1975. Associated with WIPO, Japan also participates in the following treaties: the Paris Convention for the Protection of Industrial Property (1899), the Bern Convention for the Protection of Literary and Artistic Works (1899), the Universal Copyright Convention of 1952 under UNESCO (1956), the Patent Cooperation Treaty (PCT) (1978), the Union for the Protection of New Varieties of Plants (UPOV) (1982). Japan also has a branch office of the Association Internationale pour la Protection de la Propriété Industrielle (AIPPI) (1956) and now has its own organization called AIPPI-JAPAN. On the other hand, Japan does not participate in the following treaties: Hague (1925), Rocarno (1968), Vienna (1973) and Lisbon (1958.) Furthermore, in recent international debates, Japan has not fully participated. It has not signed the FAO International Treaty on Plant Genetic Resources for Food and Agriculture of November 2001 or the Cartagena Protocol on Biosafety for the Convention on Biological Diversity of January 2000. These abstentions are principally due to concerns about the protection of intellectual property rights (IPR) that may not synchronize with the WIPO, General Agreement on Tariffs and Trade (GATT), Trade-related Aspects of Intellectual Property Rights (TRIPS) and World Trade Organization (WTO) matters. In the near future, when IP matters are better understood in domestic debates and corresponding law settings are made, Japan may agree to active participation in these important international treaties. What is more, the World Summit on Sustainable Development (WSSD) meeting, which was held in 2002 at Johannesburg, could force Japan to participate promptly in these international rules for active collaborations.

Benrishi or patent attorney

It is very difficult to obtain a permit to become a patent attorney, or Benrishi as it is called in Japan. Only an average of 3% of the applicants successfully pass tedious and cumbersome qualification examinations. There is no systematic way to train such human resources. Only a limited number of private tutorial schools offer courses to pass these examinations; however, there is no professional educational system to teach how to become an effective Benrishi. In addition to the attorney capacity, a Benrishi is required to have a specialization in given subjects equivalent to a PhD. Private sector companies have resources for preparing patent applications before requesting an attorney to handle the legal documentation processes. Consequently, many researchers with PhDs and with science and technology backgrounds are encouraged by their employers to obtain a patent attorney certification.

Besides having a technology speciality, patent attorneys now are required to have a greater legal capacity so they can handle patent infringement lawsuits. The Patent Attorney Law Partial Amendment Bill was approved in the Diet on 11 April, and was proclaimed on 17 April. The Amendment states:

> The number of intellectual property right infringement lawsuits has doubled in the last ten years (from 311 cases in 1991 to 610 cases in 2000) and is expected to increase further. On the other hand, the number of [those who have registered as] attorneys at law specializing in intellectual property has remained at less than 300. Compared with the USA (where the number of registered patent attorneys is approximately 16,000) it is difficult to render sufficient services. There have been strong demands from the 'user side' for strengthening and enrichment of dispute resolution services by means of a qualitative and quantitative increase in such expert representatives in lawsuits.Under such circumstances, it is necessary to provide intellectual property right patent attorneys (Benrishi) with the authority to act as counsel in patent right infringement lawsuits.
>
> To provide patent attorneys (Benrishi) with authority to act as counsel in intellectual property infringement lawsuits (limited to cases in which attorneys at law are involved as counsel) and for this purpose take measures to afford a high a level of reliability to patent attorneys who desire to obtain this right to act as counsel. Patent attorneys are required in principle to appear in court together with the attorney at law jointly undertaking the case. Patent attorneys can, however, attend court on their own when determined by the court as appropriate.

Since the previous edition of this book (Watanabe *et al*., 1998), there has been a major increase in the number of patent attorneys specializing in biotechnology and biological resources. However, only a few experts are available in the area of agricultural biotechnology, as industry and investors do not see a rapid domestic growth of this area and a far weaker competitive ability with international major companies such as Syngenta and Monsanto.

Intellectual properties at academic institutions

IPs are currently not systematically managed and protected in academic institutions. Unlike US academic institutions, Japanese universities merely have an office or research foundation that takes care of some issues associated with proprietary materials and technology derived from university activities. In the IPR application processes, protection and negotiation of IPs, lack of an IPR administrative office causes complicated problems for individual researchers/producers of IP that should be protected. Also, in the case of licensing and settlement for royalty fees, individual owners face various inconveniences when dealing directly with the processes, as only partial support is usually available from the administrative office at a university. The employees at public institutions cannot conduct profit-oriented negotiations during working hours, because it is considered illegal to handle profit-oriented activities, although a slight compromise may be offered by the government in the near future. Often these inventors/producers of IP materials tender all rights to the private sector; in return they receive limited compensation for their research programmes and universities. A similar situation applies to central and local governmental agencies.

There is increasing attention on IP matters at public research institutions through: (i) encouraging patents application filing; (ii) incentive pay and promotion considerations associated with patents; (iii) institutional regulation of IP matters associated with penalties if not followed; and (iv) legal enforcement of IPR and fighting infringements. With biotechnology and biological resources, more action is taking place with: (i) more attention given to IP protection of biological resources and overall research outcomes; (ii) formal documentation and authorization processing of the transfer of biological resources; and (iii) conformity of ethics associated with IPR matters.

Relationship between intellectual property rights and agriculture

Plant variety protection laws

Japan has been a member of UPOV since 1982 and follows its Revision of March 1991. While new varieties based on agricultural biotechnology could be protected by two major laws, patent and plant variety protection, double protection is not allowed in Japan. Also, it seems that Japan is far behind and making only slow progress in getting consensus and making associated legal rules in the areas of newly emerging agricultural biotechnology and variety development. However, due to the establishment of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (FAO-IT on PGR-FA), Japan is now obliged to review and revise its domestic laws associated with plant varieties and their propagation.

Seed and seedling laws

Dual controls on agrobiotechnology are associated with plant cultivars. Registration of a new variety is one means of control and the production of certified seed is the other. Registration of new cultivars can be done easily through a short application. However, production of certified seeds of many crop varieties is strictly regulated by the government. This dual control structure provides protection through registration protecting the breeder, yet may discourage the private sector because of the strict governmental control. However, it may encourage the domestic seed/seedling industry because of quarantine enforcement on strong competitors.

Biodiversity

Japan has been a member country of the Washington Convention (CITES, Convention on International Trade in Endangered Species of Wild Fauna and Flora) since 1980. Although the international trading of endangered species has been prohibited in Japan under CITES since the Convention came into effect, the domestic trading and business of endangered species within Japan was permitted until 1995. Japan is also a member of the Convention on Biological Diversity (CBD) (1993), and is considering accepting the CBD revision on biotechnological aspects, particularly on genetically altered organisms, which was agreed in January 2000 as the Cartagena Protocol on Biosafety. This protocol came into effect on 11 September 2003. The Japanese government has approved the domestic law corresponding to the Protocol, and it will be implemented at the end of 2003. However, Japan has not yet ratified the Protocol; this will happen after the domestic law enters into force in Japan. Japan has also made its own law on the conservation of endangered species, which came into effect in 1994.

The Japanese government also set a national strategy on biological diversity in 1995 in order to conserve biodiversity and enable sustainable utilization of species. Within the context of the biological diversity strategy there are three categories: ecosystem, species and genes. The national strategy considers: (i) biodiversity in Japan and globally; (ii) fundamental national indices and long-term perspectives on conservation of biodiversity and sustainable utilization; (iii) policies, laws, acts and planning for implementation; (iv) interdisciplinary approaches among central and local governments, the private sector and individual Japanese citizens; and (v) continuous self-examination and feedback for possible revisions.

One issue associated with biological diversity enforcement in Japan could be the weak recognition of genetic resources (IPR) in private sector companies, academic institutions and individual citizens compared with other developed countries. While there has been a reduction in the number of illegal transactions of biological resources overseas by Japanese

individuals or organizations, many Japanese private companies associated with agrobiotechnology still conduct 'secret' exploitation of plant genetic resources (PGR) in many PGR-rich countries. Some Japanese companies do not arrange official processes for germplasm acquisition and transfer. In many cases, these have been caused by improper brokers/facilitators of germplasm exploitation and international transfer, and also by the lack of recognition of the international treaties and movements. However, there are new efforts and a small industry emerging in Japan to properly broker the access of biological resources under the spirit and information of the Bonn Guideline on access and benefit sharing of biological resources for the Convention on Biological Diversity and particularly the FAO-IT on PGR-FA.

There is no integration of the international and national germplasm repository system in Japan. Presently duplicated efforts are made among institutions mainly under two ministries, those of Agriculture, Forestry and Fishery (MAFF), and of Education, Culture, Sports Science and Technology (MEXT). These germplasm banks independently handle whole aspects of plant genetic resources. Synchronization of banking and international relationships is weak among these public agencies. Currently there is some advancement on integration of the genebank/bioresources system, as funding was increased at MEXT. MEXT will make available about US$50 million for Japanese academic institutions to set up a system exclusively for conservation and service of genetic resources developed since 2002 and to develop a national biological resources forum. The Institute of Physical and Chemical Research Bioresources Centre (known in Japan as RIKEN) is one party to such efforts, along with its subsidiary body, the National Institute of Technology and Evaluation (NITE). It will be some time before the effectiveness of these efforts can be measured.

Pitfalls in Japanese intellectual property rights laws

The weakest and most critical area in IP management in Japan is associated with computer software. For example, public recognition of software IPR is very low compared with other developed countries and there are no major laws against computer hackers. Because of this, the price of computer and software products is very high, which makes a vicious circle of small markets. The expensive commodity price may allow illegal materials to become available at competitive prices, or even free of charge.

The IPR laws are under the supervision of the Patent Agency and the Agency for Culture Affairs. In contrast, the Seed and Seedling Law is under the MAFF. Additionally, several ministries associated with corresponding IP materials, such as the Ministry of Economics, Trade and

Industry (METI), MEXT and the Ministry of Health, Welfare and Labour, could influence the granting and implementing of IP protection. The interaction and harmonization of systems among these agencies are relatively weak compared with what other developed countries have. Thus, with respect to the agrobiotechnology area, two or more agencies may have inconsistent rules between them, which may inconvenience applicants for IP protection and potential users of a protected IP. A good example is with the biosafety and food safety rules on genetically engineered organisms: they are regulated by more than five governmental agencies with inconsistent rules.

Commercialism and National Linkages and Technology Transfer to Third Parties

Major issues in Japanese bioindustry: R&D and commercialization

Biotechnology in Japan is not merely used to develop new production methods, but also has extensive applications in the development of new pharmaceuticals, agrochemicals, seeds and seedlings, livestock and fish, and also new reactions based on engineered enzymes. Biotechnology research in Japan covers a wide range of areas from the elucidation of biological mechanisms to the development of new functional materials, such as artificial complements to human organs such as bones, teeth and blood vessels.

Although Japanese bioindustry is very large in regard to assets and investments and is growing rapidly, there are several factors or issues that may adversely affect the future of these companies. One issue is sustained research funding for biotechnology projects. Another is the availability of human resources to carry out interdisciplinary studies in areas such as plant biotechnology – identifying a critical mass of scientists to conduct long-term studies. Adequate facilities in which to conduct this research are essential, along with new and state-of-the-art equipment. And the final issue is time and the recognition by the government, industry and consumers that it will take time, probably years, to bring many new biotechnology products to market.

In the field of plant biotechnology, it will be necessary to develop fundamental and long-term industrial investments in the following areas: (i) developing new varieties using tissue culture, cell biology and molecular biology tools together with conventional breeding techniques; (ii) building a profitable and rustic plant nursery system that mass-produces clean seeds/propagules; and (iii) establishing a bioreactor system that facilitates the development of secondary metabolites, artificial and natural enzymes and non-conventional substances, such as vaccines for human diseases.

Because of the risk of failure, the expense of long-term R&D and building and retaining scientific teams, METI has been providing support for more than 10 years through a project titled 'Research & Development Project of Basic Technology for Future Industries'. This project covers such areas as bioreactors, large-scale cell cultivation, utilization of recombinant DNA, molecular assembly for functional proteins and production and utilization of technologies of complex carbohydrates. Each programme under the project is funded for multi-million dollars per year for several years. These research programmes are getting attention in Japan and overseas as a way to conduct R&D for the future. There are several major multi-year biotechnology projects funded by other ministries and their subsidiary bodies. Some patents have been obtained; however, it seems that so far the driving forces for industrial applications and commercialization of these patented technologies are weak.

The second major problem facing Japanese bioindustry is protecting IPR. Biotechnology is a discipline covering a wide range of basic and applied research, development and product production. Because of the broad spectrum of biotechnology, it has become increasingly difficult for a private company to monopolize or even know about all the possible patents for a single product. It is possible that one company might unknowingly use the patented technology of another inappropriately. Therefore, the possibility of patent infringement problems ending up in court is increasing, resulting in great cost of time and money. Also, laws are different from country to country, although international treaties are in effect in many countries. In the case of a new plant variety, because the prohibition of double protection has been eliminated, it is unclear as to how patent laws and plant variety protection laws should be applied.

Proprietary biotechnology transfer has been conducted with developing countries, especially Asian nations in three major modes: (i) ODA basis (Takase, 1994; Kainuma, 1995); (ii) private sector investment (Sumida and Nishizawa, 1995); and (iii) independent initiatives (Kozai *et al.*, 1993; Altman and Watanabe, 1995; Watanabe and Pehu, 1997). The key pitfalls on proprietary technology transfer are: (i) scarce human resources for facilitating the entirety of the technology transfer activities; (ii) lack of interest in philanthropic technology transfer in the private sector; and (iii) lack of recognition and understanding of proprietary-material-handling by public agencies.

A third issue is that of biosafety. Safety issues and public acceptance of genetically modified organisms (GMOs) associated with agricultural biotechnology have been increasing concerns in Japan. The major factors are biosafety regulatory issues and public understanding of the potential of GMOs.

There have been two schools of thought with respect to the safety evaluation of biotechnology. The first is a process-oriented approach, in that biotechnology is a special technology and that safety evaluation is

necessary wherever a biotechnology-based process is used in any product, regardless of the type of final product, be it a crop or a live vaccine. The second is a product-oriented approach, in that whether biotechnology is used or not, safety evaluation should be conducted on each product based on scientific knowledge in each product field as well as experiences acquired through use of the products.

Another issue is that education has not been properly provided for the public, who might consume biotechnology products, making an informed decision about whether or not to use biotech products difficult (Zechendorf, 1994). Japan has been poor at providing public enlightenment and continuing-education programmes (Macer, 1994, 1997). Gradually, consumers' associations and concerned individuals are being advised on the introduction of agrobiotech products mainly from the USA as possible consumables on a daily basis. As of January 1997, products derived from seven transgenic cultivars (soybean, canola, potato and maize) from North America were approved for importation. Now is the time both for public and private agencies to discuss how the agrobiotech products can be recognized and used.

Weak status of agrobiotechnology industry in Japan

In contrast to North American and European biotech associations, Japan has no systematic structure for IP protection and licence negotiation by public bodies such as industry associations. As previously mentioned, there are no special services rendered in this biotech area by patent attorneys, although there are more than 500 patent attorney offices in Japan. It appears that a facilitator or business consultant in this area is surely needed to promote proprietary agrobiotechnology.

Overall, Japan could be regarded as a silent player in the area of agricultural biotechnology (Okada, 1996). The Japanese private sector has lost opportunities due to its rather careful approach and patriotic individualism that neglect partnerships and consultative services from overseas. Key patents on plant biotechnology have been swept by North American and European private companies (Stone, 1995), which has strongly and adversely affected Japanese companies. Japanese bioindustry faces many obstacles associated with IPs in international aspects, especially in North America. These obstacles include: (i) the complication of patenting inspection (O'Shaughnessy, 1996); (ii) the tendency of granting wider coverage of patentable subjects such as DNA sequences (Agris, 1996); (iii) changing of laws on patentable 'process' (Van Horn and Barlow, 1996); and (iv) slow follow up on the litigations of IPR issues on agrobiotechnology. It appears that Japanese senior managers and investors have been rather timid in the agrobiotech industry, resulting in the loss of opportunities in acquiring IPR protection and potential profits.

Sectorial reforms for retrieving the international competitiveness

IPR policy revision

The Japanese Patent Office (JPO) completed formulation of the 'Patent Policies for 2005' on 17 April 1998. A statement about this revision is as follows: 'To achieve the goals in the "Patent Policies for 2005", the whole organization of the JPO will positively address itself to the promotion of patent administration. The main policy stays with the "Global contribution toward pro-patent age", and the following three components are the basis: 1) the era of intellectual creation; 2) globalization of economy; and 3) the advent of network technology.'

The implementation of the policies was planned as follows:

1. World leading operation: (i) speeding up the granting of patent protection going from 22 months to 12 months to real time operation; (ii) providing high quality examination; and (iii) improving customer satisfaction.
2. Effective utilization of patents: (i) creating and developing patent markets; (ii) providing support for venture companies, and (iii) improving the dispute settlement mechanism.
3. Globalization of IPR policies: (i) urging a worldwide patent; (ii) promoting international cooperation; and (iii) globalizing patent applications.
4. Patent information highways: (i) developing a cyber patent office; and (ii) establishing a digital patent library.

IPR Licensing Organizations and Patent Integration

While there have been many IPR organizations in Japan, no strong organization exists to integrate and/or license IP protected technology from academic institutions and, in general, from public organizations. Establishing systems for patent integration and licensing are gradually reducing this weakness. For example, the New Industry Research Organization (NIRO), developed by local governments, has as its function the integration of available patents, particularly the patents owned by the Japanese government, in order to license them effectively for industrial applications. Also, since the law for the promotion of technology transfer from academic institutions was established in August 1998, many Japanese universities have established technology licensing offices (TLOs). As of August 2002, 29 TLOs were approved or accepted by governmental authorities. These TLOs may be incorporated as a private firm, a part of university function or a tax-exempt foundation.

Support for start up/venture companies has been emerging, with business consultation and investment being made by venture-capital firms such as Patent Capital Inc. Examples of the major investors for venture business on biotechnology are listed in Table 12.2.

Table 12.2. Examples of venture capital companies based in Japan whose investments are in Japan.

Company	Website	Date incorporated
BioFrontier Partners, Inc.	www.biofrontier.co.jp/toppage1.htm	10 March 1999
Japan Asia Investment Co., Ltd	www.jaic-vc.co.jp/eng/index.html	10 July 1981
JAFCO Co., Ltd	www.jafco.co.jp/eng/home/index.html	5 April 1973
Nikko Capital Inc., Ltd	www.nikko-capital.co.jp	15 July 1983
UFJ Capital Co., Ltd	www.ufjcapital.co.jp	1 August 1984
Patent Capital Inc., Ltd	www.pcinc.co.jp/pci_main.shtml	17 November 1998

Integration of Industry for IPR Enforcement

In Japan, integration or merging of companies in agrobiotechnology has begun. For example, Mitsubishi Chemical, which is the seventh largest revenue generator in the world, is the result of merging Mitsubishi Kasei and Mitsubishi Petroleum (Anon., 1996c). Similarly, Mitsui Petroleum Chemical has merged with Mitsui Toatsu Chemical to form Mitsui Chemical.

Other biotech initiatives in the private sector include both domestic and international connections. Such an example is the flower biotech company made by Kirin (Okamura and Kagami, 1997). Foreign companies have also penetrated Japanese industries, for example Orynova Co. Ltd, which is a joint venture on rice biotechnology made by Japan Tobacco and Zeneca. Now Orynova is a subsidiary of Syngenta. Suntory, a Japanese company, created a subsidiary firm in July 2002. This subsidiary, Suntory Flowers Co. Ltd, specializes in flower biotechnology R&D and sales of its products. The company is at present one of the rare winners using agricultural biotechnology originated in Japan. Through the development of very competitive petunia and carnation varieties, the company is realizing profits and providing a financial return for the company. This success can be highlighted through the following steps taken by the company: (i) acquisition of proprietary germplasm; (ii) protection of these technologies; (iii) cutting costs of laboratory management; (iv) including long-term development of human resources; (v) out-sourcing of labour-intensive but simple works; and (vi) investing in academic institutions through collaborative and/or contract research, particularly on basic research, and requiring a means to license new proprietary materials developed through this research.

Thus, by gathering or combining capital, assets, infrastructure, technology, market networks and human resources, some Japanese private companies are rejuvenating and re-enforcing their international competitiveness. Cross licensing and royalty settlement of proprietary biotech-

nology are also ongoing between Japanese biotech companies and international agrobiotech giants such as Monsanto. Also, industry associations are now assisting companies in avoiding various pitfalls leading to business failure. This is similar to what was arranged in Germany by its bioindustry association (Anon., 1996b). With these factors and strong leadership at Japanese firms, Japan will be prepared to take part in the proprietary biotechnology business arena. What is more, as the Japanese government increases its aid in overall R&D in several areas, including biotechnology, this will enable both the private and public Japanese sectors to enter and compete in international markets with their own proprietary materials.

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India

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Introduction

India, as a member of the World Trade Organization (WTO) since 1 January 1995, is obliged to keep its trade policies within the boundaries set by the WTO agreements. India preferred to classify itself as a developing nation and, with respect to the Trade-related Intellectual Property Rights (TRIPS), India has made significant progress in bringing most of its domestic intellectual property laws to comply with the TRIPS standards.

A Historical Backdrop to Intellectual Property Rights in India

The concept of intellectual property rights (IPR) is not new in India. From the 16th and 17th centuries, the Portuguese, Dutch, French and British established commercial and colonial interests in India (Bose *et al*., 1971). In order to exploit the natural resources and local talent to the full, the British introduced modern scientific methods and education in India, and India maintained a competitive commercial edge in trade. As competition from other European countries grew, the British introduced an Act of Protection of Inventions, based on the British Patent Law of 1852, which was enacted in India in 1856. By this Act, certain privileges were granted to the inventor for new methods of manufacture. Later changes to the law in this field were the Patents and Designs Protection Act 1872 and the Protection Inventions Act, which was introduced in 1883 and consolidated as the Invention and Designs Act in 1888, followed by the Indian Patents and Designs Act of 1911 (Narayan, 1985).

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Indian patents and designs came under the management of the Controller of Patents and Designs on 15 August 1947. After independence, this Act was nationalized (Chand, 1950; Ayyangar, 1959). A Patents Bill was introduced into Parliament in 1965, but did not go through, so an amended Bill was introduced in 1967 that resulted in the Patents Act of 1970, which, together with the rules, came into force on 20 April 1972. This Act is known as the Indian Patents Act 1970, which has undergone major changes in the form of two amendments, namely the Patents Amendment in April 1999 and a second one in May 2002. These features will be elaborated in later sections of this article.

The Designs Act was brought into India in 1872 to extend protection to textiles, linen, cotton, calicoes and muslin; this included patterns/prints and modelling, casting and embossment of ornaments or articles of manufacture. The next development was the Indian Patent and Designs Act, which came into force in 1911 with amendments in 1978, with the rules amended in 1985.

The Indian Designs Act 2000 has replaced the Designs Act of 1911 and is compliant with TRIPS. The salient changes in the Designs Act 2000 are:

- Enlarging the scope of definition of the following terms: (i) 'article': to mean any article of manufacture and any substance, artificial, or partly artificial and partly natural, and to include any part of the article capable of being sold separately; (ii) 'design': to mean only features of shape, configuration, pattern, ornamentation or composition of lines or colours applied to any article whether in two-dimensional or three-dimensional or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction or anything that is in substance a mere mechanical device, and does not include any trademark as defined in clause (v) of subsection (1) of Section 2 of the Trade Marks Act 1958 or property mark as defined in Section 479 of the Indian Penal Code or any artistic work as defined in clause C of Section 2 of the Copyright Act 1957; (iii) 'original': in relation to a design, to mean originating from the author of such design and to include cases that, though old in themselves, yet are new in their application.
- Amplifying the scope of 'prior publication' to include any design that has been disclosed to the public anywhere in India or in any other country by publication in tangible form or by use or in any other way prior to the filing date or where applicable, the priority date of the application.
- Provision for substitution of applicant before registration of a design.
- Substitution of Indian classification by internationally followed system of classification.

- Provision for restoration of lapsed designs.
- Provisions for appeal against orders of the Controller before the High Court instead of Central Government.
- Revoking of period of secrecy of 2 years for a registered design.
- Providing for compulsory registration of any document for transfer of rights in the registered design.
- Introduction of additional grounds in cancellation proceedings and provisions for initiating the cancellation proceedings before the Controller in place of the High Court.
- Enhancement of quantum of penalty imposed for infringement of registered design.
- Provision for grounds of cancellation to be taken as defence in the infringement proceedings to be initiated in any court not below the District Judge.
- Enhancing initial period of registration from 5 to 10 years, to be followed by a further extension for a period of 5 years.
- Provision for allowance of priority to other convention countries and countries belonging to the group of countries or intergovernmental organizations apart from the UK and other Commonwealth countries.
- Provision for avoidance of certain restrictive conditions for the control of anti-competitive practices in contractual licences.

Design applications are examined in the Designs Wing under the Patent Office in Kolkalá. It receives and examines applications relating to the registration of designs from both Indian and foreign applicants.

Legislation to protect trademarks came into force on 6 June 1942 and was based on the principles of English Common Law. The Act of 1940 was further amended to the Indian Trade and Merchandise Marks Act 1958, which came into force on 25 November 1959.

The Trade Marks Act 1999, which came into effect on 15 September 2003 with the notification of the Rules, has now replaced this Act of 1958 and is compliant with TRIPS. The salient features of the Indian Trade Marks Act 1999 are:

- inclusion of trademark for services in the definition of trademark;
- a new provision for registration of Collective Marks;
- a single Register of Trade Marks instead of two parts – Part A and Part B;
- prohibition of registration of certain marks that are mere reproductions or imitations of 'well-known' marks;
- provisions for filing a single application for registration in more than one class of goods and/or services;
- increasing the term of registration of a trademark from 7 to 10 years and providing a grace period of 6 months for payment of renewal fees;
- amplification of circumstances in which validity of registration can be contested;

- vesting the final authority in the Registrar for disposing of application for registration of Certification Trade Marks;
- harmonizing penal provisions of the Trade Marks Law with the Copyright Law; and
- provision for establishment of an Appellate Board.

A Copyright Act was passed for the first time in India in 1914. The Copyright Act 1957 adopted several principles of the British Copyright Act 1956 to cope with the emerging problems created by technological advances in communication, broadcasting, microfilming, movies, etc.

Amendments to the Copyright Act 1957 were made in 1983, 1984, 1992, 1994 and recently in 1999. The amended Act incorporates various aspects that are information-technology led and at the same time encompasses neighbouring rights including performer's rights, protection of rights of broadcasting organizations, etc. The amendments in 1999 brought the Indian Copyright Law in compliance with TRIPS.

For the first time, India introduced and brought into force the Geographical Indications of Goods (Registration and Protection) Act 1999 with the Rules in 2002.

The salient features of the Geographical Indications Act 1999 are:

- provision of definition of several important terms like 'geographical indication', 'goods', 'producers', 'packages', 'registered proprietor', 'authorized user', etc.;
- provision for the maintenance of a Register of Geographical Indications in two Parts – Part A and Part B – and use of computers, etc. for maintenance of such a Register. While Part A will contain all registered geographical indications, Part B will contain particulars of registered authorized users;
- registration of geographical indications of goods in specified classes;
- prohibition of registration of certain geographical indications;
- compulsory advertisement of all accepted geographical indications and providing provisions for taking infringement action, either by a registered proprietor or an authorized user;
- provisions for higher level of protection for notified goods;
- prohibition of assignment, etc. of a geographical indication as a public property;
- prohibition of registration of geographical indication as a trademark;
- appeal against Registrar's Decision would be to the Intellectual Property Appellate Board established under the trademarks legislation;
- provision relating to offences and penalties;
- provision detailing the effects of registration and the rights conferred by registration; and
- provisions for reciprocity, powers of the Registrar, maintenance of index, protection of homonymous geographical indications, etc.

India has taken a major initiative to develop and enact a novel Protection of Plant Varieties and Farmers' Rights Act 2001 (PPVFR 2001), which not only introduces provisions for the protection of new plant varieties, but also builds into the legislation features to protect farmer's rights and provides an administrative framework for benefit sharing between the beneficiaries, etc., which in combination with the Indian Patents Act/Trade Marks Act/Geographical Indications Act/Biodiversity Act will significantly impact on the IPR status in activities related to agriculture and agricultural biotechnology in India. The PPVFR 2001 in many ways may be considered as a model act for developing and the least developed nations.

New Intellectual Property Rights-related Acts Impacting on Agriculture and Agricultural Biotechnology in India

The Protection of Plant Varieties and Farmers' Rights Act 2001

India has chosen the option of not allowing patenting of plant varieties but having a separate *sui generis* system to deal with protection of innovations in these fields of technology leading to registration for plant breeders' varieties, extant varieties, farmers' varieties and essentially derived varieties.

The key aspects of this new Act are as follows.

1. Establishment of the Protection of Plant Varieties and Farmers' Rights Authority consisting of a Chairperson and 15 members appointed by the Central Government.
2. Setting up of a Plant Varieties Protection appellate Tribunal to deal with any appeal on order or decision of the authority or Registrar relating to registration of the variety, registration of an agent or a licensee of a variety, claim for benefit sharing, revocation of compulsory licence or modification of compulsory licence, or payment of compensation under the Act or its rules.
3. Establishment of the Plants Variety Registry. For the purposes of the Act, a Register called the National Register of Plant Varieties would be established in the Registry, which contained entries of all the names of the registered plant varieties with names and addresses of their respective breeders in respect of the registered variety, the particulars of the denomination of each registered variety, its seed or other propagating material along with specification of their salient features.
4. Registrable varieties should satisfy the criteria of novelty, distinctiveness, uniformity and stability (NDUS).

Application for registration of any variety may be made for: (i) a genus and species other than those excluded as per notification of the

Central Government; (ii) a plant that is an extant variety; or (iii) a plant that is a farmer's variety.

A few definitions are essential to appreciate the nuances of the Act:

1. *An essentially derived variety* (EDV) is a plant that: (i) is predominantly derived from such initial variety, or from a variety that itself is predominantly derived from such initial variety, while retaining the expression of the essential characteristics that result from the genotypes of such initial variety; (ii) is clearly distinguishable from the initial variety; and (iii) conforms (except for the differences that result from the act of derivation) to such initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of such initial variety.
2. *An extant variety* (EV) means a variety available in India: (i) notified under Section 5 of the Seeds Act 1966 (54 of 1966); (ii) a farmer's variety; or (iii) any other variety that is in the public domain.
3. *Denomination* in relation to a variety or its propagating material or essentially derived variety or its propagating material means the denomination of such variety or its propagating material or its essentially derived variety or its propagating material as the case may be, expressed by means of letters or a combination of letters and figures written in any language.

Novelty, distinctiveness, uniformity and stability

The criteria for novelty are that, at the date of filing of the application for registration for protection, the propagating or harvesting material of such variety has not been sold or otherwise disposed of by or with the consent of its breeder or his/her successor for the purposes of exploitation of such variety: (i) in India earlier than 1 year, or (ii) outside India, in the case of trees or vines earlier than 6 years, or (iii) in any other case, earlier than 4 years.

The criteria for distinctiveness, uniformity and stability have their usual meanings. However there are some unique features that the denomination must satisfy to qualify as a registrable variety, and it cannot be registered if the denomination given to such variety:

- is not capable of identifying such variety;
- consists solely of figures;
- is liable to mislead or to cause confusion concerning the characteristics, value, identity of such variety, or the identity of the breeder of such variety;
- is not different from every denomination that designates a variety of the same botanical species or of a closely related species registered under the Act;
- is likely to deceive the public or cause confusion in the public regarding the identity of such variety;

- is likely to hurt the religious sentiments, respectively, of any class or section of the citizens of India;
- is prohibited for use as a name or emblem for any of the purposes mentioned in Section 3 of the Emblems and Names (Protection of improper use) Act, 1950 (52 of 1950); or
- is comprised solely or partly of a geographical name.

It should also be noted that any denomination assigned to a variety shall not be registered as a trademark under the Act.

The applicant is expected to assign a single and distinct denomination to a variety with respect to which he is seeking registration under the Act. Furthermore, the application must contain the passport data of the parental lines from which the variety has been derived, along with the geographical location from where the genetic material has been taken and all such information relating to the contribution, if any, of any farmer, village community, institution or organization in breeding, evolving or developing the variety. It must also contain a declaration that the genetic material or parental material acquired for breeding, evolving or developing the variety has been lawfully acquired.

The applicant is also expected to provide the Registrar a quantity of seeds of a variety for which the application is being made for the purpose of conducting tests to evaluate whether the seeds of such variety, along with its parental material, conform to the standards as specified by the regulations.

The application for registration, on acceptance by the Registrar, subject to his/her satisfaction with it together with amendments if any, is advertised with the specifications, photographs or drawings to enable interested parties to file opposition to the registration within 3 months of the date of the advertisement.

In the case of registration of an EDV, the variety must satisfy the conditions of NDUS, as in the case of 'varieties'. The Registrar, after satisfying himself/herself of the conditions of NDUS, will forward the application to the Authority who will have it tested to determine whether the EDV is a variety derived from the initial variety. If the report is in order then the Authority will direct the Registrar to register the EDV.

The grounds for opposition are: (i) that the person opposing the application is entitled to the breeder's rights as against the applicant; (ii) that the variety is not registrable under this Act; (iii) that the grant of certificate of registration may not be in the public interest; or (iv) that the variety may have an adverse effect on the environment.

The opposition proceedings are to be conducted on similar lines to the opposition of patents in which the Registrar gives an opportunity to the applicant to submit his counterstatement, leading with evidence by the opponent, followed by a hearing if necessary, culminating with the decision by the Registrar.

In the case of an application for registration of a variety (other than an EDV) that has satisfied all the conditions as laid down by the Act, the Registrar will register the variety, issue a certificate of registration to the applicant and send a copy of the same to the Authority for determination of benefit sharing.

The registration certificate is valid for 9 years in the case of trees and vines and 6 years in the case of other crops and may be reviewed and renewed for the remaining period on payment of the prescribed fees, subject to the total period of protection not exceeding: (i) 18 years from the date of registration of the variety in the case of trees and vines; (ii) 15 years from the date of notification of the variety by the Central Government under Section 5 of the Seeds Act 1996 in the case of extant varieties; or (iii) 15 years from the date of registration of the variety in other cases.

The Act has a unique provision for 'benefit sharing' for Indian organizations (firms, governmental or non-governmental) and group(s) of persons who are Indian citizens who would be allowed to stake claim to the benefits accruing from a registered variety. The Authority would publish the contents of the issued certificate, and possible beneficiaries, as defined earlier, may submit their claims for benefit sharing. The Authority would then send a copy of this claim to the breeder for opposition, if any, from his/her side. After hearing both the parties, the Authorities would dispose the claim received. While disposing the claim, the Authority would explicitly indicate in its order the amount of benefit sharing, if any, for which the claimant is entitled and would take into consideration the following aspects: (i) the extant and the nature of the use of the genetic material of the claimant in the development of the variety; and (ii) the commercial utility of and demand for the variety in the market.

The amount of benefit sharing determined under the section on 'benefit sharing' shall, on reference made by the Authority, be recoverable as an arrear of land revenue by the district Magistrate within whose local limits of jurisdiction the breeder liable for such benefit sharing resides.

The breeder is expected to deposit an adequate quantity of the seeds or the propagating material, including the parental material line of the registered variety, in the National Gene Bank for reproduction purposes at the breeder's expense within a period as specified in the order of the Authority.

Registration confers rights on the breeder or his/her successor, agent or licensee to produce, sell, market, distribute, import or export the variety as per the Act subject to the limitations and conditions specified in the regulations. However, in the case of an EV, unless a breeder or his/her successor established his/her right, the Central Government and, in cases where such EV is notified for a State or for any area thereof under Section 5 of the Seeds Act 1966, the State Government shall be deemed to be the owner of such right. For the licensee or an agent to become entitled to produce, sell, market, distribute, import or export a variety, he/she has to

apply to the Registrar to register his/her title, and only on satisfactory proof of entitlement and resolution of any disputes will the Registrar issue him/her with a certificate of registration with a record of all the conditions and entitlements. There are specific conditions in the Act under which such a registration certificate may be cancelled.

The Authority may, with prior approval of the Central Government by notification in the Official Gazette, impose a fee to be paid annually by every breeder of a variety, agent and licensee thereof registered under the Act, determined on the basis of the benefit or royalty gained by such a breeder, agent or licensee, as the case may be, in respect of the variety, for retention of their registration under the Act. If the breeder, agent or licensee fails to pay the prescribed fees consecutively for 2 years, then the Authority will serve a notice to such a breeder, agent or licensee. Failure to comply with such a notice leads to the forfeiture of the registration certificate by the Authority. The arrears of the fees would then be considered as arrears of land revenue and would be recovered accordingly.

The Act includes a section on Researcher's Rights, which allows the use of: (i) any variety registered under the Act by any person using such a variety for conducting experiments or research; and (ii) a variety by any person as an initial source of variety for the purpose of creating other varieties.

This section also requires the authorization of the breeder of a registered variety for repeated use of such a variety as a parental line for commercial production of such another newly developed variety.

The Act has a special provision relating to application for registration from citizens of convention countries and provisions as to reciprocity as required by a treaty, convention or arrangement with any country and India. As in the case of patents, there is a priority of 12 months for any application for registration of a variety made in any convention country.

Revocation of a registered variety is possible on the following grounds, as specified in the Act:

1. The grant has been based on incorrect information furnished by the applicant.
2. The certificate has been granted to a person who is not eligible for protection.
3. The breeder did not provide the Registrar with such information and documentation as required by the Act.
4. The breeder failed to provide an alternative denomination of the variety that is the subject matter of registration to the Registrar in a case where the earlier denomination of such variety provided to the Registrar was not permissible for registration by the Act.
5. The breeder did not provide the necessary seeds or propagating material to the person to whom compulsory licence has been issued regarding the variety in respect of which the registration certificate has been issued.

6. The breeder has not complied with the provisions of the Act or rules or regulations.
7. The breeder has failed to comply with the directions of the Authority issued under the Act.
8. The grant of the certificate of registration is not in the public interest.

The breeder in every case will be given the opportunity to file an objection and be heard in any matter related to the revocation of his registration.

There is a special provision for Farmers' Rights in the Act that gives a farmer:

- the right to register the farmer's varieties;
- the right to benefit sharing for use of biodiversity by the breeder, which is conserved by the farming community; any person, group of persons or any governmental or non-governmental organization may, on behalf of the village community in India, file any claim attributable to the contribution of the people of that village or local community, as the case may be, in the evolution of any variety for the purpose of staking claim on behalf of such local community. The authority, after due consideration of such claims based on the facts and their investigations, may issue a notice to the breeder, and after providing him/her with an opportunity to be heard, by order, may grant such sum of compensation to be paid to a person, group of persons or governmental or non-governmental organization who has made the claim. The breeder of the variety would deposit any such compensation to the National Gene Fund;
- the right to save, use, sow, re-sow, exchange, share or sell farm produce including seed of the registered variety;
- the right to claim compensation from the breeder for underperformance of the variety from the promised level;
- the requirement to seek consent of the farmer(s) when the farmer's variety is used to develop an EDV;
- protection from legal proceedings of an alleged innocent infringement by the farmer; and
- exclusion from paying fees in any legal proceedings in Tribunal and Higher Courts.

The Central Government would provide a fund called the National Gene Fund, which is credited with:

- benefit sharing received from the breeder of a variety or an EDV or propagating material of such variety or EDV;
- the annual fees payable to the Authority by way of royalties;
- the compensation deposited by the breeder in the Gene Fund; and
- contributions from any national and international organization and other sources.

The Gene Fund is to be used for paying the amounts from benefit sharing and/or compensations payable to the beneficiaries, expenditure to support the conservation and sustainable use of genetic resources including *in situ* and *ex situ* collections, and for strengthening the capability of the local village administration (Panchayat) to carry out such conservation and sustainable use and any expenditure of the schemes for the exemption of paying fees in any legal proceedings in Tribunal and Higher Courts by the farming community.

The Act puts in place an elaborate provision on compulsory licences in certain circumstances. Essentially it states that any time after the expiry date of 3 years from the date of issue of the registration certificate for a variety, any person interested may make an application to the Authority alleging that reasonable requirements of the public for seeds or other propagating material of the variety have not been satisfied, or that the seed or other propagating material of the variety are not available to the public at a reasonable price, and they may request the grant of a compulsory licence to undertake production, distribution and sale of the seed or other propagating material of that variety. The Authority would give the breeder of such a variety an opportunity to file an opposition to the application of compulsory licence and, after hearing both parties, decide on the matter of compulsory licence. The Authority, based on a written request from the breeder of the variety, may adjourn the hearing of the application of the compulsory licence for a period of 12 months, if the breeder is able to reasonably justify to the Authority his/her reasons for not being able to produce the seed or the propagating material of the variety on a commercial scale to an adequate extent until the date of making such a request.

If the Authority deems it fit, it may order the breeder to grant a compulsory licence to the applicant and send a copy of such order to the Registrar to register the title of such applicant as licensee on payment of the appropriate fees by the applicant. The duration of the compulsory licence would vary on a case-by-case basis. The reproductive material of the variety relating to the compulsory licence would be stored with the National Gene Bank or any other centre authorized by the Central Government. The authority would set the terms and conditions of the compulsory licence and decide on 'reasonable compensation to the breeder of the variety' based on the nature of the variety, the expenditure incurred by the breeder to develop the variety and other relevant factors. The Authority would also take into consideration the ability of the compulsory licensee to produce the seed or its propagating material and to make it available to the public at a reasonable price. The compulsory licence may be revoked or modified by the Authority under certain circumstances.

All suits for infringements are instituted in any court inferior to a District court having jurisdiction to try the suit.

Actions that are considered as infringement are: (i) selling, exporting, importing or producing a registered variety without the permission of the breeder/licensee/registered agent by a person who is not the breeder of the registered variety or a registered licensee or agent, or is involved in activities that are not within the registered scope of the licence or registered agency, as the case may be; and (ii) using, selling, exporting, importing or producing any other variety giving such variety a denomination identical or deceptively similar to the denomination of a variety in such a manner as to cause confusion in the minds of general people in identifying such variety so registered.

Relief in the case of infringements includes an injunction and, at the option of the plaintiff, either damages or a share of profits. Under certain circumstances, the injunction may include *ex parte* or an interlocutory order.

There is a penalty for applying false denomination, etc. Any person who applies any false denomination to a variety, or indicates the false name of a country or place, or false name and address of the breeder of a registered variety in the course of trading such variety, unless he/she proves that he/she acted without intent to defraud, is punishable with imprisonment for a term of not less than 6 months but which may be extended to 2 years, or with a fine, which is not less than 50,000 rupees (approximately US$1000) but which may extend to rupees 5 lakhs (approximately US$10,000).

Similarly any person who sells, or exposes for sale, or has in his/her possession for the purpose of trade or production any variety to which any false denomination has been applied or to which an indication of the country or place of such variety has been made or produced, or the name or address of the breeder of such registered variety has been falsely made, unless he/she proves: (i) that the necessary due diligence was exercised to check the genuineness of the denomination; (ii) that, on demand by or on behalf of the prosecutor, all information in his/her possession was given with respect to the person from whom he/she obtained the variety; or (iii) that otherwise he/she had acted innocently, shall be punishable with imprisonment for a term that shall not be less that 6 months, but which may be extended to 2 years, or a fine of 50,000 rupees to rupees 5 lakhs.

Falsely representing a variety as registered or an EDV as registered is also a punishable offence, with imprisonment for a term not less than 6 months, but which may be extended to 2 years, or a fine of 50,000 rupees to rupees 5 lakhs.

Procedures have been provided so that an accused in the above situations may plead invalidity of the registration of a variety as part of the proceedings.

The Biological Diversity Act 2002

Both houses of the Indian parliament passed the Biological Diversity Act 2002 on 11 December 2002 to provide for the conservation of biological diversity in India, sustainable use of its components and equitable sharing of benefits arising out of the use of biological resources in the country. The definition of 'biological diversity' includes the variability among living organisms from all sources and the ecological complexes of which they are part and also includes diversity within species or between species and the ecosystem. The meaning of 'biological resources' is defined as plants, animals and microorganisms or parts thereof, their genetic material and by-products with actual or potential use or value, but does not include human genetic material. The Act makes provision for the setting up of a regulatory body called the National Biodiversity authority (NBA) as well as State-level Boards that would look into the utilization of biological resources for research and development purposes within the country and the respective states. Some of the salient features of the Act that impact on agricultural biotechnology research and development (R&D) and commercialization in India are:

1. No person who is not a citizen of India, or who is a non-resident Indian as defined in clause 30 of Section 2 of the Indian Income Tax Act 1961, or a corporate body/organization/association not incorporated or registered in India or incorporated/registered in India under any law for the time being in force that has any non-Indian participation in its share capital or management shall without previous approval of the NBA obtain any biological resource occurring in India or knowledge associated thereto for research or commercial utilization or for biosurvey or bioutilization.
2. Approval of the NBA is necessary for the transfer of results of any research relating to any biological resources occurring in or obtained from India for monitory consideration or otherwise to any person who is not a citizen of India or a corporate body or organization that is not registered or incorporated or that has any non-Indian participation in its share capital or management.
3. Any IPR application in or outside India based on any research or information on biological resources obtained from India must be done with the previous approval of the NBA. Even if an application for a patent is made, the person must obtain the approval of the NBA after its acceptance but before the patent is sealed.
4. The NBA, while granting the approval, may impose benefit sharing fees and/or royalty or both, or impose conditions including the sharing of financial benefits arising out of the commercialization of such rights.
5. No person who is a citizen of India or a corporate body, association or organization, which is registered in India, shall obtain any biological resource for commercialization or biosurvey or bioutilization except after

giving prior intimation to the State Biodiversity Board concerned. This provision does not apply to the local people and communities, including those who have been practising indigenous medicine.
6. The penalty for not abiding by the regulations includes 3 years of imprisonment and a fine of rupees 5 lakhs (approximately US$10,000) and the offences would be considered as cognizable and non-bailable.

The Central Government has formulated national strategies, plans and programmes for the conservation and sustainable use of biological resources, including measures for identification and monitoring of areas rich in biological resources, promotion of *in situ* and *ex situ* conservation of biological resource incentives for R&D, training and public education to increase awareness with respect to biodiversity. It also assesses projects for their adverse effects on biological diversity, with a view to avoiding or minimizing such effects and, where appropriate, uses public participation for such assessment. The Central Government also regulates, manages and controls the risks associated with the use and release of modified organisms resulting from biotechnology likely to have adverse impact on the conservation and sustainable use of biodiversity and human health. The State Governments have created a 'local biodiversity fund' to be used for the conservation of the local biodiversity and for the benefit of the local community.

The Biological Diversity Act 2002 together with the Protection of Plant Varieties and Farmers' Rights Act and the Patent Act 1970 (amended) will significantly impact on any IPR strategy and its implementation in the field of agricultural biotechnology. Hence a holistic understanding of the issues involved is essential.

Amendments to the Patent Act 1970 and other developments

India joined the Paris Convention and the Patent Cooperation Treaty in December 1998 and also became a signatory to the Budapest Treaty in 2000. India also brought in amendments to the Indian Patent Act in two stages in April 1999 and in May 2002.

The Patent Act 1970 and subsequent amendments in 1999 and 2002

The Patent Act of India 1911 was fairly liberal, as patenting of products related to foods, pharmaceuticals, chemicals, etc. was available with a full term of 16 years. This was directly in line with the British Patent Act of 1907. India follows the 'first-to-file' system as in most countries. The Indian Patent Act 1970 brought in significant changes with restrictions related to the patenting of inventions and in the areas of chemicals, pharmaceuticals, agrochemicals and foods, in which product patents had been discontinued and patenting of processes with a restricted life of 7

years from the date of filing of the complete specification (or 5 years from the date of sealing the patent, whichever is shorter) was introduced. This protected patent regime provided a safe platform on which pharmaceutical and chemical industries could strike roots and grow in India and could also meet the need to increase production rather than relying on imports, which was critical for the national economy.

FIRST AMENDMENT TO THE PATENT ACT 1970 ENACTED IN 1999 WITH RETROSPECTIVE EFFECT FROM 1 JANUARY 1995 The restrictions outlined in sections 3, 4 and 5 of the Indian Patents Act 1970 are in direct conflict with the Articles 27(1), 27(2) and 27(3) of the TRIPS Agreement. As mentioned earlier, India decided to class itself as a developing nation and take advantage of the full term of 10 years that would be available to it to introduce the product patent regime before 1 January 2005.

As a transitory arrangement, the first set of amendments introduced into the Patents Act 1970 were intended to provide a means in the Act for the filing of patent applications for pharmaceutical or agricultural chemical products (as required by subparagraph (a) of Article 70.8 of the TRIPS Agreement) and for the grant of exclusive marketing rights with respect to the products that are the subject of such patent applications (as required by Article 70.9 of the Agreement).

Section 5 subsection (a) and (b) of the unamended Patents Act 1970 does not allow the granting of product patents for foods, drugs, medicines or even substances prepared or produced by chemical processes, including alloys, optical glass, semi-conductors and intermetallic compounds. Only process patents are allowed in these areas.

The first amendment in 1999 makes it possible to file product patents for inventions related to drugs and medicines only. However, product patents cannot be filed for inventions related to foods and other chemically prepared entities.

This transitory arrangement for the patent applications for drugs and medicines is only meant to gain priority, but these applications will not be referred to an examiner by the controller until 31 December 2004 or until the Indian Patent Act is changed to allow product patents, whichever is earlier.

The term 'medicines or drugs' includes:

1. All medicines for internal or external use for human beings or animals.
2. All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals.
3. All substances intended to be used for or in the maintenance of public health, or the prevention or control of disease among human beings or animals.
4. Insecticides, germicides, fungicides, herbicides and all other substances intended to be used for the protection or preservation of plants.

5. All chemical substances that are ordinarily used as intermediaries in the preparation or manufacture of any of the medicines or substances above referred to.

THE AMENDMENT AND EXCLUSIVE MARKETING RIGHTS A major change is the inclusion of a pipeline protection of 5 years for drugs and medicines after filing a product patent application on or after 1 January 1995. These products can qualify for the granting of exclusive marketing rights (EMR) provided that certain conditions are fulfilled.

The controller will not refer all applications made under this amendment to an examiner until the Patent Act is changed to allow product patent or until 31 December 2004, whichever is earlier. However, the application would be examined on submission to ascertain that the application does not fall within Section 3 and Section 4 of the Indian Patents Act 1970, which define categories of inventions for which a patent cannot be granted. Only inventions that do not fall within the purview of section 3 and section 4 (i.e. satisfy the criteria of patentable invention) would qualify for consideration of EMR in India.

A special provision in the amended Act states that any substance or article based on the System of Indian Medicine as defined in clause (e) of sub-section (1) of section 2 of the Indian Medicine Council Act 1970 and such substance or article already in the public domain will not qualify for the granting of EMR in India.

To obtain EMR (pipeline protection) for a product, for which applications are filed in India exclusively in the areas of drugs, pharmaceuticals and agrochemicals such as insecticides, germicides, fungicides, herbicides and all other substances intended to be used for the protection or preservation of plants, the applicant would have to meet the following requirements:

1. *Inventions made in India or in a country other than India*. Prior to filing an application for a product patent in India and applying for EMR, the applicant must have filed an application for a patent in any convention country for an identical invention on or after 1 January 1995. The patent and the approval to sell or distribute the article or product on the basis of appropriate tests conducted on or after 1 January 1995 in that country must have been granted on or after the date of making the patent application in India.
2. *Inventions made in Indi*a. Prior to filing an application for a product patent in India and applying for EMR, the applicant must have filed a patent application in India for the process relating to the identical product on or after 1 January 1995. The applicant should process the patent granted in India prior to the filing of an application for EMR.
3. For both of the above categories, the applicant for EMR in India must have received the approval to sell or distribute the article or substance from the authority specified in this behalf by the Government of India.

The term of the EMR is 5 years on or from the date of approval granted by the controller until the date of the grant of the patent or the date of rejection of application for the grant of patent, whichever is earlier.

If the invention for which the product patent application is being made has been recorded in a document, or the invention has been tried or used before, or the article has been sold by a person before the claim for a patent (i.e. a product patent application has been filed) of that invention is made in India or in a convention country, then the sale or distribution of the article or substance by such a person after the claim referred in the patent application shall not be deemed to be an infringement of EMR.

Before granting EMR, the controller will have to: (i) ascertain that the application for the product patent is a patentable invention under sections 3 and 4 of the Indian Patents Act 1970; (ii) conduct any other investigations he/she deems necessary; and (iii) ensure that all other conditions outlined in the ordinance are satisfied.

OTHER ISSUES IN THE FIRST AMENDMENT These are as follows:

1. Sale and distribution of the article in India would be considered as working of the invention. The interpretation of working of a patent in the Patent Act before the first amendment was 'manufacturing'.
2. Clauses (c) and (d) under section 90 dealing with the importation and working of the patent were deleted. This implied that importation would be considered as working of the invention in India. Prior to the first amendment, importation was not considered as working of a patent in India.
3. In the public interest, the Government has reserved the right to intervene while granting EMR and issuing of compulsory licences. The Government also reserves the right to decide on the pricing of articles covered under the EMR.
4. All suits relating to infringement of an EMR will be dealt with in the same manner as if they were suits concerning infringement of patents under Chapter 18 of the Patents Act 1970.

The first amendment to the Patent Act 1970 brings in continuity with respect to all actions taken under the ordinance of 1994 as if this first amendment came into effect on 20 May 2003, and was operative from 1 January 1995.

THE SECOND PATENT AMENDMENT (1999) TO THE PATENT ACT 1970 IN 2002 WITH PATENT RULES 2003 The second amendment in continuation of the first amendment came into effect on 20 May 2003 with the notification of the Rules, and addresses the following issues.

- Harmonization of the patent term to 20 years, irrespective of the filed technology.
- Publication of the patent application after 18 months of filing.

- Faster prosecution of patent applications and transparency in the whole process.
- Reversal of the burden of proof of process when there is an infringement of process patents. As per the TRIPS requirement, the alleged infringer will have to prove that he/she is not infringing the process patent.
- Effective framework for enforcement.
- Conditions for 'working of patents', 'compulsory licensing', 'opposition' and 'revocation'.
- The 'Bolar-like' provisions.

The amendment has made a few significant additions and deletions from the list of inventions that are not patentable in India. The amended section 3 dealing with inventions that are not patentable is as follows.

- An invention that is frivolous or that claims anything obviously contrary to well-established natural laws.
- An invention, the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.
- The mere discovery of a scientific principle, or the formulation of an abstract theory, or the discovery of any living thing or non-living substance occurring in nature.
- The mere discovery of any new property or new use for a known substance, or of the mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant.
- A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process of producing such substance.
- The mere arrangement or rearrangement or duplication of known devices, each functioning independently of one another in a known way.
- A method of agriculture and horticulture.
- Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.
- Plants and animals in whole or any part thereof other than microorganisms, but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.
- A mathematical or business method or a computer program *per se* or algorithms.
- A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions.

- A mere scheme or rule or method of performing a mental act or method of playing a game.
- A presentation of information.
- Topography of integrated circuits.
- An invention that, in effect, is traditional knowledge or that is an aggregation or duplication of known properties of a traditionally known component or components.

A new feature in the amended Act is that software *per se* is not patentable. This clarification is important as it suggests that if software satisfies conditions of patentable inventions and are linked to applications, etc., their grant should not be rejected.

The exclusions state 'other than microorganisms', suggesting that microorganisms in principle have not been excluded from patentability, which is very important and significant.

It may be recalled that section 5 of the Indian Patent Act 1970, after the first amendment in 1999 under the title 'Inventions where only methods or processes of manufacture are patentable', read as follows:

> In the case of inventions: (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and intermetallic compounds), no patent shall be granted in respect of claims for the substances themselves but claims for the methods or process of manufacture shall be patentable.

The text of the second amendment clarifies that for the purposes of this section, 'chemical processes' includes biochemical, biotechnological and microbiological processes.

1. In section 10 of the Indian Patent Act 1970 dealing with the contents of a patent specification, amendments have been introduced, additions to include the following requirements for biological materials, namely that the specification shall be accompanied by an abstract to provide technical information on the invention.

2. If the applicant mentions a biological material in the specification that is not described in such a way as to satisfy clauses requiring the disclosure with the best method of performing the invention such that anyone trained in the art can reproduce the invention, and if such material is not available to the public, the application shall be completed by depositing the material to an authorized depository institution as may be notified by the Central Government in the Official Gazette and by fulfilling the following conditions, namely:

(a) the deposit of the material shall be made not later than the date of the patent application in India;
(b) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification

including the name, address of the depository institution and the date and number of the deposit of the material at the institution (as per the Budapest Treaty of which India is a signatory);

(c) access to the material is available in the depository institution only after the date of the application for patent in India or if a priority is claimed after the date of the priority; and the source and geographical origin of the biological material must be disclosed in the specification, when used in an invention.

India continues to follow the 'first-to-file' and the 'pre-grant ' systems, even after the amendments to the Patent Act 1970. Under the pre-grant system, the patent application, after examination and acceptance by the Patent Controller, is advertised in the Gazette of India and anyone interested in opposing the accepted application can file an opposition petition with the Patent Office within 4 months of the date of publication of the specification. If any of the parties is dissatisfied with the decision of the controller, he/she can file an appeal with the Appellate Board to be set up as a result of the second amendment to the Patent Act 1970.

The grounds for opposition as per the second amendment now include, among other clauses:

- the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; and
- the invention so far as is claimed in any claim of the complete specification is anticipated with regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

Similarly, the grounds for revocation of a patent, in addition to the usual grounds, now also include:

- the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; and
- the invention so far as is claimed in any claim of the complete specification is anticipated with regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

These additional grounds have been brought in to correct for any wrongful use of indigenous biological resources and traditional knowledge, and bring the Patent Act in line with the Protection of Plant Varieties and Farmers' Rights Act 2001.

Working of patents and compulsory licensing in the amended act

The second amendment has deleted sections 86, 87 and 88 of the Indian Patent Act 1970 dealing with the practice of 'licences of right' thereby complying the requirement of TRIPS on this issue.

Section 83 dealing with the general principles applicable to the working of patented inventions has been expanded to include several conditions, in particular:

- that patents are granted to encourage inventions and to ensure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
- that patents granted do not impede protection of public health and nutrition and should act as instruments to promote public interest especially in sectors of vital importance for socio-economic and technological development of India;
- that patents granted do not in any way prohibit Central Government from taking measures to protect public health;
- that the patents right is not abused by the patentee or person deriving title or interest on the patent from the patentee, and the patentee or a person deriving title or interest on the patent from the patentee does not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology; and
- that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

It may be noted that the broadening of the conditions for 'working of patents' has brought this section into conflict with the amendments made in 1999 and 2002. The first amendment clearly states that importation would be considered as working of a patent in the context of EMR. However, section 83 after the second amendment has chosen to cloud the issue by introducing broad qualifiers in section 83 of the amended Act.

Along similar lines, section 84 of the amended Act strengthens the earlier grounds for compulsory licences in that, at any time after the expiration of 3 years from the date of the sealing of a patent, any person interested may make an application to the Controller for grant of compulsory licence on the patent on any of the following grounds, namely:

- that reasonable requirements of the public with respect to the patented invention have not been satisified;
- that the patented invention is not available to the public at a reasonably affordable price; or
- that the patented invention has not worked in the territory of India.

As per section 84 of the amended Act, the Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the patented invention is not worked in the territory of India, or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence to the applicant of a compulsory licence upon such terms as he may deem fit. The Controller may also direct the patentee to grant a licence by exercising his powers set out in section 88 of the amended Act, which allow him to consider issues related to 'unfair licensing arrangements, compulsory licensing of dependent and essential patents such the work one, the other patent is essential', etc.

In considering the application field for compulsory licence, the Controller shall take into account: (i) the nature of the invention, the time that has elapsed since the sealing of the patent and the measures already taken by the patentee or any licence to make full use of the invention; (ii) the ability of the applicant to work the invention to the public advantage; (iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted; and (iv) whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and whether such efforts have been successful or not within a reasonable period as the Controller may deem fit.

It should be noted that these clauses are not applicable in the case of national emergency or other circumstances of extreme urgency, or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

The reasonable requirements of the public shall be deemed not to have been satisfied if:

- By reason of the refusal of the patentee to grant a licence or licences on reasonable terms,
  - (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or
  - (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufacture in India is not being supplied or developed; or
(iv) the establishment or development of commercial activities in India is prejudiced; or

- by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced, or
- the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grantback, prevention to challenges to the validity of patent or coercive package licensing, or
- the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or
- the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by:
  (i) the patentee or person claiming under him/her; or
  (ii) persons directly or indirectly purchasing from him/her; or
  (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

Though on one side the conditions under which the compulsory licences to be granted have been eased, the terms for 'fair returns' to the patentee in the case of compulsory licences granted are debatable in the amended Act as it states in section 90, 'The royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and keeping in force and other relevant factors.'

Similarly, as per the special provisions (national emergency) in section 92 (1) (ii), the Act states that 'in setting the terms and conditions of a license granted under this Section, the Controller shall endeavour to secure the articles manufactured under the patent shall be available to the public at the lowest price consistent with the patentee deriving reasonable advantage from their patent rights.'

The sections relating to compulsory licensing and the grounds set for 'fair compensation to the patentee' in the event of issuance of a compulsory licence are contentious and debatable. They appear much in favour of the licensee of a compulsory licence and might not adequately protect the interest of the 'innovator.'

This is further borne out in section 90 (1) (ii), which sets the terms and conditions for Compulsory Licensee where the stated objective is to ensure that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him/her.

Such hyper-protective measures in the long term could affect the National Innovation System and have an impact on the Foreign Direct Investments (FDI), especially in fields related to high technology.

It should also be noted that India has yet to introduce an effective system for data protection that is compliant with article 39.3 of TRIPS. This is currently being debated. Some government sources have argued that a system for data protection is in place via the existing National Official Secrets Act, as it binds public servants from disclosing or using confidential information in an unauthorized manner that may affect the security, sovereignty and integrity of the country.

A key question is whether the protection under the Official Secrets Act provides appropriate and adequate protection to originator's for their proprietary test data and whether it mandates the government not to disclose or rely on the proprietary data for the marketing approval of 'generic' ('follower') copies of the pharmaceutical products without the explicit approval of the originator, at least for a reasonable period. Another point to be debated is whether the Official Secrets Act provides the necessary protection with built-in mechanisms within the meaning of the Act for the originators to enforce their rights for the proprietary test data. Even the US Trade Secret Laws have proved to be inadequate in protecting proprietary data submitted to regulatory authorities. The position of the courts in exploiting the Trade Secret Laws in the USA and elsewhere in the event of the authorities relying on the data submitted to them earlier by the originator to evaluate the application of the 'follower' is not clear. Moreover, a few cases have been decided on 'public policy' grounds, but the difficulties faced by the originators have been inordinately high.

One may also argue that the 'Exclusive Marketing Rights' (EMR) conferred under Article 70.9 of TRIPS for pharmaceutical and agricultural chemical products provides for indirect protection of the data submitted by the 'originator', who secured such authorization and designation. In principle, EMR stops a second applicant for authorization during the term of the EMR even if the 'follower'/generic company generates its own data. However, the concept of EMR is organically connected to the originator having obtained a patent and approval to market the drug in at least one member country of the WTO. It obviously does not protect the test data of items that either are not patentable or for which patents have not yet been granted. It may be noted that EMR was introduced in India via the first amendment to the Patent Act of 1970 in April 1999 but made retrospectively effective from 1 January 1995.

The issues related to patents will gain clarity only when India takes the next crucial step by 1 January 2005, when it is supposed to comply with all the requirements of TRIPS, in particular satisfying the requirements of the 'product patents regime'.

The IPR regime in India continues to be in a state of dynamic transition. The subsidiary legislations by way of Rules to several of the amended Acts are yet to be put in place. The Acts relating to Competition and Protection of Undisclosed Information are also in their formative stages. India also needs to consider its National IPR policy with respect to biotechnology with a sense of urgency. The IPR scene in India is therefore expected to change significantly in the next few years, especially in fields related to life forms, including plants, animals, environment, agriculture and biotechnology.

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Intellectual Property Rights in the Russian Federation

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Current Obstacles and Trends in Intellectual Property Rights Development

While Russians better understand how intellectual property functions in a market economy today, little more than 10 years after the Russian Duma (legislative assembly) passed the first intellectual property rights (IPR) legislation, there is, at this writing, no viable IPR market in the Russian Federation. A number of obstacles remain.

- The Russian economy is not focused upon innovation as an engine for economic development. Generally, Russian corporations do not consider an IPR portfolio as a strategic business asset or resource for enhancing the value of their business.
- There are very few patent specialists in IPR law and management in the Russian Federation with any significant market experience. Furthermore, a new type of skill set is needed for patent specialists today, compared with the patent agents of the Soviet era.
- Ownership of IPR resulting from research funded by the Government is poorly defined and a clear obstacle to commercial development of those research results.
- Few successful case studies of the commercial development of IPR by Russian companies exist to provide examples and encouragement to Russian innovators.
- Risk capital is scarce in the Russian Federation, and the venture resources that do exist do not consider investment in 'seed stage' opportunities, or 'embryonic' technologies emerging from research institutes, universities and individual inventors.

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- Intangible assets were not appraised in establishing book value for new enterprises during the rapid business privatization in the Russian Federation in the 1990s. Realization of intangible asset value has led to numerous disputes and conflicts that have negatively impacted on the IPR market.
- Also, as a result of rapid privatization of state institutes and enterprises, there is no clarity as to the ownership of inventions formerly held by the state-owned enterprises.
- The scepticism of the general population and business towards efforts to legislate change in embedded Russian systems is an intangible but important barrier to treatment of IPR in the Russian Federation.
- Most importantly, enforcement of rights in intellectual property (IP) under Russian laws is weak, with few courts or judges knowledgeable about the importance or principles of IP.

Present Intellectual Property Rights Laws, Policies and Practices

In the former Soviet Union, with the absence of a tradition of private ownership of property, IPR law was based on principles of collective ownership, and focused on dissemination of creative works and inventions to the population, rather than protecting the individual rights of inventors. In contrast, the Constitution of the Russian Federation of 12 December 1993 clearly established that IP would be protected in the new Government, with a goal of bringing Russian IPR law into accord with Western practices. Furthermore, during the early 1990s, the Russian Duma enacted legislation in an effort to place the legal base for IP protection in the Russian Federation on a par with international standards.

Patent rights

The Patent Law of the Russian Federation (Federal Law No. 3517–1, 23 September 1992) established principles for protection of: (i) inventions; (ii) utility models; and (iii) industrial designs, on a par with international standards.

The owner of a Russian patent possesses a monopoly: the exclusive right to use the claimed invention, as well as the right to prohibit others from using the invention. The broad term 'use' is defined to include the production, use, exporting, importing, marketing and selling of the patented invention; any such use by a third party without the owner's authorization is considered an infringement. Contrary to the previous Soviet system, a patent is now an instrument that gives its owner distinct commercial advantages.

Inventions

Inventions include devices, processes, methods and substances, as well as cell cultures and microorganisms. An invention must possess three basic characteristics to be eligible for protection: novelty, inventiveness and industrial applicability.

- Novelty requirements are absolute: the innovation as claimed must not previously have been made public, in any form of published information in the Russian Federation or internationally, or in prior Soviet patents, inventions, certificates, or applications for patents or certificates.
- Inventiveness is comparable to the 'non-obvious' requirements in the Western legal model: the innovation must not be obvious to one skilled in the art of the invention at the time of conception of the invention. While inventiveness is very subjective, the Regulations on Design, Applying and Examination of Patent Applications (Rospatent Order No. 82, 17 April 1998) provide specific instructions and criteria to examiners in the Russian Agency for Patent and Trademarks, or Rospatent (www.fips.ru), in making such subjective analysis.
- Industrial application requires the invention to have utility or application in industry, agriculture, medicine and other legitimate business activities.

It should be noted that these definitions of patentability correspond to the former Soviet definitions, as Russian patent examiners have significant experience with these definitions.

Patent protection is not available for the following types of innovations: scientific theories; mathematical methods and algorithms; computer programs; methods of economic organization and management; conventional signs, schedules and rules; methods of mental health therapy; architectural designs for buildings; topology of microchips; varieties of flora and fauna; and any inventions that are '…contrary to social interests and principles of humanity and morality'.

APPLICATION The patent application must be filed with Rospatent in Moscow with the following minimum requirements: (i) a petition specifying the names of the inventor and the owner; (ii) a detailed description of the invention, sufficient for one to practise the innovation; (iii) the claims of the invention, expressing its unique features; (iv) design drawings, as appropriate; (v) an abstract; and (vi) payment of the applicable fees.

EXAMINATION Examination of an application is divided into two phases: preliminary examination and substantive examination.

1. *Preliminary examination*. First, Rospatent ensures that the application includes all required documentation, properly completed. Furthermore, Rospatent ensures that the invention indeed is an innovation for which patent protection can be sought under Russian law. Rospatent must conduct the preliminary examination within 2 months.
2. *Substantive examination*. Within 3 years of the filing date, the applicant may petition for substantive examination. During this process, Rospatent: (i) ensures that the application meets the priority filing date in accordance with international standards; (ii) ensures that the application meets the basic criteria for protection (novelty, inventiveness, industrial application); and (iii) examines the unique features of the claims of the invention according to the requirements of Rospatent Order No. 82.

On average, Rospatent makes a decision of allowance within 30 months of receipt of the application. The patent term extends for 20 years from the filing date. If the application is rejected by Rospatent, the applicant may appeal to the Rospatent Appeals Chamber, which makes its ruling within 4 months. Finally, if the application is again refused, an appeal may be filed with the Supreme Patent Chamber, whose decision is final.

Utility model

The Russian utility model – or 'small invention' – has no parallel in the Western legal model. Only mechanical/electrical devices qualify as utility models; other innovations, such as processes, methods, substances, cell cultures and microorganisms, are precluded from protection as utility models.

APPLICATION The application for a utility model certificate must be filed with Rospatent in Moscow with the same documentation as for an invention.

EXAMINATION The examination process for a utility model is much less rigorous than for an invention patent. Only a preliminary examination of a utility model is made, with no substantive examination, to ensure that all documentation has been completed properly. Rospatent will issue the certificate if the application contains all required documentation and the description of the device is sufficiently detailed. Furthermore, no level of inventiveness is required; although novelty is addressed, the standards are much less rigorous than for inventions. The applicant must assume full responsibility for achievement of standards and validity; no guarantee of validity may be assumed by issuance of the utility model certificate by Rospatent.

Utility model certificates are valid for 5 years from the filing date, and may be extended by petition and payment of fees, but only for an

additional 3 years. On average, Rospatent makes a decision of allowance within 1 year of the filing date, compared with an average of 3 years for an invention. Once the certificate is issued, the owner may exclude others from making, using or selling the device, as does the owner of a patent for an invention.

Industrial designs

Patents issued for industrial designs protect only the outward appearance of an object. A design is patentable if it is novel, original to the designer and has industrial application or utility. Originality requires only a unique creative or aesthetic appearance of an article. Industrial application or utility assumes that the design could be repeatedly reproduced by means of manufacturing. Protection is not available for architectural designs for buildings, printed works, objects that are not fixed in form, or any articles that are contrary to social interests and principles of humanity and morality. Finally, industrial design patents do not protect the functionality of the object.

APPLICATION An application for an industrial design patent must include: (i) a petition to Rospatent identifying the designer and the owner; (ii) photographs or drawings that graphically show the outward appearance of the object; (iii) design drawings if necessary to fully describe the unique features of the design; (iv) a written description of the design; and (v) payment of fees.

EXAMINATION Industrial design patents are subject to identical requirements of examination as patents for inventions: preliminary examination and substantive examination.

The term of an industrial design patent is 10 years from the filing date. The term may be extended by owner petition and payment of fees, but for no longer than 5 additional years.

Inventorship and ownership

Under Russian law, an inalienable personal right accrues to the inventor, who must be a native, and is recognized with no limitation of time. However, inventors may assign ownership of a patent to a third party by contract for consideration. Additionally, in the absence of an agreement to the contrary, title to inventions made by employees within the scope of their official employment lies with their employer. However, as a unique feature of Russian patent law, if an employer fails to file a patent application after 4 months of being informed of the invention, then ownership of the invention reverts to the employee.

Accordingly, potential licensors of patents should investigate the relationship between employee and employer before executing an agreement for rights to a patent. 'Bad practices' or disagreements between employees and employers regarding ownership are not unusual and can be a significant barrier to IPR commercialization. Surprisingly, there are no laws or court case practices for resolving such disagreements in the Russian Federation.

In the case of multiple or joint owners of a patent, the relationship and responsibilities between the joint owners are determined by contract. In the absence of any contract, each owner can use the invention. However, unlike US law where there is no accounting required between joint owners of a patent, Russian law states that no joint owner can license rights in a patent to third parties without authorization from the other joint owner(s).

Other features of Russian patent law

- Citizens of the Russian Federation may file patent applications with Rospatent personally, while citizens of foreign countries must make an application to Rospatent through a registered Russian IP attorney.
- Russian law adheres to the 'first-to-file' principle adopted by most countries, rather than the 'first-to-invent' principle of the USA.
- Patent applications are published 18 months after application, although the inventor may petition that his or her name be withheld from the publication.
- Patent rights may be licensed – exclusively or non-exclusively – by licence agreement, or even assigned to a third party. However, no licence or assignment agreement is valid unless it is properly registered with Rospatent. Registration procedures do not require prior approval, but simply recording of the existence of the licence or assignment agreement.
- A product, process or composition of matter is infringing if it utilizes substantially all of the unique features described in an issued patent.
- Prior user rights are recognized in the Russian Federation, i.e. the exclusive rights of a patent owner may not be enforced against any person or company that can prove that it was practising the invention (without seeking patent protection and in the absence of publication), prior to the issuance of the patent. However, the practising person or company cannot increase production of the protected invention once the patent is allowed.
- While Russian law requires that patent infringement questions be submitted to the applicable court (the specific court is dependent upon case-specific circumstances under the patent law), such cases are few; no significant practice of enforcement of patent rights has been established in the Russian Federation.

Copyrights

The Law on Copyright and Neighbouring Rights (Federal Law No. 5351-1) was adopted in July 1993 for the protection of original works of authorship in science, literature and the arts ('authors' rights'), as well as for the protection of the rights of performers such as productions, performances, musical recordings and radio broadcasts ('neighbouring rights'). As in the West, authors' rights protect an original form of expression and not the underlying ideas, methods, processes and systems, nor may factual data be protected. Russian law is based upon the principle of original creativity; the author's ownership of the work extends from its creation, and no official registration with the Russian Government is required. In keeping with international norms, the author may place the standard copyright symbol and notice on the work to inform the reader or author of intent to claim copyright. In 1995, the Russian Federation joined international copyright conventions and agreements (Paris, Bern and Geneva Conventions).

Similar to international norms, authors are afforded moral rights and economic rights to their works. Moral rights are inalienable and personal, with no time limitation, and include recognition of authorship, the right to publish and use the creation, and the right to protect the work from revisions or derivatives that would harm the author's reputation.

Economic rights are transferable and include the right to use the work of authorship in any form, including for reproduction, distribution by any means, sale, leasing, import, export, etc.; the list is not exhaustive as 16 rights accrue to the author in the Law on Copyright and Neighbouring Rights. It should be noted that should the author transfer economic rights in the work to a third party, the transfer is not valid unless all 16 rights are specifically enumerated in the licence or assignment agreement. The term of economic rights is defined as the duration of the author's life plus 50 years after the author's death.

Russian copyright law presumes validity of authorship, unless contested by another party. Authors may license or assign their economic rights in copyrightable works to third parties by licence agreement or assignment agreement. Additionally, if the work is created within the scope of an employee's responsibility, it is considered a 'work for hire', with title to the work residing in the employer.

As stated, there is no requirement to register a copyrightable work with Rospatent or any other Russian Federation office. However, registration is a common practice. Registration of a literary or artistic work is made with the Russian Authors' Society. Software and databases may be registered with Rospatent with an application consisting of a petition, a sample of the software or database and payment of the applicable fees. Typically, Rospatent will provide the official registration number for the work within 2 months of the application date. Registrations are valuable as evidence of original creativity should the work be infringed.

In suspected infringement of copyright, the owner can appeal to the designated court to stop the infringement. The court may: (i) require an accounting of the income earned by the infringer from the infringing action; (ii) allow the owner to recover these losses from the infringer; and (iii) require the infringer to pay a penalty in an amount equal to 50–50,000 times the 'minimal size of salary' or MSS (the MSS currently is defined in actual practice as 100 roubles). An owner can bring a case of alleged copyright infringement before the designated court without paying any court fees or costs. If a significant sum of illegal income is derived from an infringement, the infringing party may also be prosecuted under the Russian Criminal Code.

Trademarks

The Russian Federation adopted the Law for Trade Marks, Service Marks and Names of Good's Origin (Federal Law No. 3520–1) in September 1992. Rights in marks are established by use in commerce, when usage uniquely identifies a good or a service, or distinguishes analogous goods or services of different producers or providers. Once a mark is established in commerce, its owner can register the mark with Rospatent and can prevent others from using the mark or one so similar as to cause confusion in the mind of the consumer in identifying the owner of a good or service. Unlike US law, Russian law requires official registration of a mark before the owner can exclude others from using the mark in commerce.

Legal mark protection is not available for the following: marks with no distinguishing or unique features; marks that use state arms, flags, emblems or generally recognized symbols; marks that directly indicate the type, quality, features, value or time/date of manufacture of a good; and marks that are contrary to social interests and principles of humanity and morality.

APPLICATION As stated, ownership of a mark is not official until registration is made with Rospatent. An application must include: (i) an applicant's petition for registration; (ii) a sample of the mark as used in commerce; (iii) the list of classes of commercial goods or services identified by the mark, such classes corresponding to international classifications of goods and services; (iv) a verbal description of the mark; and (v) payment of applicable fees. Citizens of the Russian Federation may file mark applications personally, while citizens of foreign countries must make the application through a registered Russian IP attorney.

EXAMINATION As with inventions, examination is divided into two phases: preliminary examination and substantive examination.

Rospatent completes the preliminary examination within 1 month of the filing date to ensure that all documentation is included in the application. Rospatent then initiates the substantive examination, which is made to ensure that the mark is distinct from other marks and that the mark does not fall into any categories for which legal protection is not available. On average, substantive examination requires 2 years. If registration is granted, the term of the protection exists for a period of 10 years from the filing date. A 10-year extension is available by petition and payment of additional fees to Rospatent.

In the case of an infringement, the owner can bring the case to the designated court. Remedies available to the owner through the court include: (i) the requirement that the infringing party stop its illegal use of the mark; (ii) removal of infringing labels from goods at the infringer's expense; (iii) publication of information about the infringing party and action in order to restore the good will of the mark's owner; (iv) recovery of losses by the owner from the infringer; and (v) payment of penalties (a new amendment to the law). It should be noted that mark infringement cases are the most common of all IP matters in the Russian court system.

Plant Varieties and Animal Breeds

While the Russian Patent Law excludes protection of plant varieties, protection is afforded under the Law of the Russian Federation on Selection Achievements (Federal Law No. 5605–1, September 1993), which also provides legal protection of animal breeds. The State Commission of the Russian Federation for Examining and Protecting Selection Achievements administers this law.

Plant varieties

A plant selection is patentable if it is novel, distinct, uniform and stable. The novelty criterion for selection achievement differs from that of inventions and means 'commercial novelty', implying that seeds or breeding material have not been sold or otherwise transferred to others in the Russian Federation earlier than: (i) 1 year from the filing date for most varieties; (ii) 4 years in another country; or (iii) 6 years for vines, decorative trees, fruit trees or forest trees. A selection is distinct if it possesses features that clearly distinguish it from any other commonly known selections of the same botanical genus. Plant selections should be uniform, taking into account minor deviations in propagation; the limits of deviation are defined in the law, making some cross-pollinated plant species ineligible for protection. Finally, a plant selection must be stable, such that its unique features remain unchanged after repeated propagation.

The breeder must file an application for plant selection achievement with the State Commission, unless the selection was created in the course of employment, in which case the right to file the application belongs to the employer. When the applicant is not the breeder, the applicant must execute an agreement with the breeder with consideration to be paid to the breeder in an amount no less than 2% of the income that subsequently may be received by the applicant from commercial exploitation of the selection. The application consists of: (i) the petition for grant of the patent; (ii) a completed questionnaire describing the distinct features of the selection; (iii) payment of fees; and (iv) a name for the selection achievement. The name must be brief and unique, distinguishing the selection from closely related botanical species.

As with inventions and trademarks, examination is divided into preliminary and substantive examinations. The preliminary examination, establishing the registration date and ensuring that all documentation is in order, is completed within 1 month. Next, the State Commission reviews the novelty, distinctness, uniformity and stability of the selection, including examination of seeds or breeding material submitted by the applicant. If the application meets all criteria for allowance and its name is sufficiently distinct, the State Commission awards and publishes the patent, typically within 6 months of the priority date.

An issued patent for plant selection achievement is valid for 30 years from the date of registration, or 35 years for vines, decorative trees, fruit trees or forest trees. The patent owner holds the exclusive right to use of the selection achievement. The owner may grant to third parties the right to reproduce, condition, market, sell, export, import and store for these purposes the selection by licence agreement. Any such licence agreement is effective only upon formal registration of the contract with the State Commission. Finally, the patent owner may also grant an open, non-exclusive licence to any interested party by publishing a notice in the official bulletin of the State Commission that the selection is available upon the payment of specified compensation.

Animal breeds

In contrast with the International Convention for the Protection of New Varieties of Plants (UPOV), Russian law provides for the legal protection of animal breeds. A breed is defined as 'an animal grouping that has genetically conditioned biological and morphological features typical for such groupings, and distinguishing it from other animal groupings'. A breed can be male or female, with specimen or breeding material (embryos).

As with plants, an animal breed selection is patentable if it is novel, distinct, uniform and stable, with principles similar to requirements for plant selections. Moreover, the application and examination procedures

are similar to those for plant selections. If the State Commission grants the patent, the owner holds the monopoly on use of the selection for a term of 30 years from the registration date.

Trends in Russian Intellectual Property Rights Legislation

Changes in various laws related to IP have had a significant impact upon the practice of IPR management in the Russian Federation. In fact, examination of the last 10 years reveals three significant trends in the focus of Russian agencies and Government officials on IPR in the national economy.

Initially, the Russian Government realized the inherent value of IPR as private property. Accordingly, to stimulate the development of IPR activity, the Government waived all taxes upon the asset value of patent rights, including the value added tax, social taxes and pension fund payments. Additionally, significant reductions in personal income taxes were made for investments in patent rights. In fact, by transfer of patent rights from one organization to another by means of licence agreement or assignment agreement, an individual or organization could receive significant sums of cash payment with no tax consequences. Unfortunately, this privilege was abused, leading to companies using patent rights agreements to minimize their tax base. As a result of these abuses, the tax advantages of patent rights agreements were eliminated in the late 1990s.

Secondly, the Russian Government realized that almost all rights in Russian innovations and IPR were transferred to new corporations and other privatized enterprises with no compensation to the Government research institutes or universities. In the period 1999–2000, in hopes of 'restoring fairness,' Russian authorities adopted a number of important decrees and regulations. The most well known of these regulations – Decree No. 982 – required that, in the absence of patenting by a private owner, all IPR should belong to the State. Subsequently, Government agencies were established to develop mechanisms for commercialization of State-owned IPR, excluding inventors from sharing rights and from participating in the commercialization process. As might be expected, these efforts failed. This period was characterized by stagnation in the IPR marketplace as a result of the uncertainty of ownership in IPR.

Finally, the current wave of interest is focused upon understanding the strategic value of IPR in commercial competitiveness, both domestically and internationally. IPR is now perceived as a potential source of income and an important tool that Russian corporations and organizations may use in maximizing assets. This current period is characterized by so-called 'new IPR thinking' at the highest levels in the Russian Government. In November 2001, Instruction No. 1607 was adopted, which announced that IPR resulting from federal or regional Government financing should be commercialized by transferring rights

to the organization that developed the innovation. For the first time, the Russian Government realized the importance of placing the first right to protect and commercialize an innovation with its creator.

Patent Rights Legislation

The only substantive change in the patent law from 1992 to 2002 was an increase in the fees for filing patent applications (2002). However, on 7 February 2003, the Duma adopted Federal Law 22-F3, On Inputting Amendments to the Patent Law of the Russian Federation. Numerous beneficial amendments were accomplished, the most important of which is clarification of ownership in IPR resulting from Government funding. Under the new law, ownership of the IPR resulting from Government-funded research lies with the performing individual or organization, in the absence of any other terms in the research contract. This principal is a great step forward in bringing the principles of IPR ownership in the Russian Federation in line with many of the industrialized countries of the world, including the USA, Japan and Germany. Furthermore, in the case where the research contract specifies ownership in the Russian Federation for defence, security or other national purposes, the Government has 6 months from the date of notification of an invention to choose to file a patent application. If the Government does not file the application within this 6 month period, ownership of the invention reverts to the inventing individual or organization. The new law was effective from 12 March 2003.

Copyright Legislation

By Government Ordinance No. 413, dated 12 April 1999, Rospatent was charged with developing legislation, international cooperation and interaction with public organizations in managing copyright protection. Additionally, Rospatent must cooperate with Executive Ministries that perform some functions for management of copyrights within their area of responsibility.

Accordingly, in 2001 Rospatent submitted to the Duma a bill entitled On Inputting Amendments to the Law of the Russian Federation on Copyright and Related Rights. This Bill seeks to improve management of copyrights as well as to bring Russian copyright law in conformity with international law and international treaties to which the Russian Federation is a party. Additionally, the law attempts to resolve the current confusion when copyright law and criminal law both may have jurisdiction in a case of infringement. The 2001 bill remains pending before the Duma.

Not all needed improvements in the copyright regime in the Russian Federation will be resolved by legislation. Appropriate enforcement of copyrights – politically, in law enforcement and in the judiciary – must be addressed. Furthermore, cooperation between Rospatent and authors' societies for collective administration and management of rights of multiple authors in a field, such as musical works, must be developed, including pricing policies corresponding to the actual values of copyrights in the Russian economy.

Trademark Legislation

Trademark law was the first of the Russian IPR laws that recorded significant revision since first adoption in 1992. The new Federal Law On Inputting Amendments to the Law of the Russian Federation on Trade Marks, Service Marks and Names of Good's Origin was adopted in December 2002, revising the 1992 law. The most significant changes are focused upon details in the application and examination processes, as well as amending the criteria for allowing or rejecting applications. Grounds for refusal of an application now include similarity of the mark to a valuable cultural object, as well as marks for alcoholic drinks used in other countries. In the case of an infringement, the new law added penalty as a remedy, wherein an infringer can be fined up to 50,000 times the MSS (100 roubles).

Additionally, a new chapter recognizes commonly known and accepted marks utilized in trade and commerce. No legal registration or examination is required for commonly known marks, with protection granted simply by petition. No time limit for protection is placed upon commonly used marks; protection is perpetual.

The most controversial change in the 2002 law is the significant increase in the cost of mark registration fees, which increased from 300 roubles per one mark to approximately 19,000 roubles per mark. While the impact of this increase remains to be seen, many individuals believe that a significant decrease in mark applications will ensue, weakening the competitiveness of Russian companies and institutions.

Other Legislation and Directives

There are a number of additional measures currently before the Russian Duma that may impact on the legal status and management of IPR in the Russian Federation, including but not limited to, proposals for: (i) additional protection for the topology of micro circuitry; (ii) additional means for protection of computer software and databases; (iii) protection for commercial trade secrets; and (iv) revisions to tax codes for stimulation of innovation development.

Additionally, recent Presidential Decrees have emphasized that Russian science, technology and innovation must be better managed and utilized for the economic development of the nation and the quality of life of the Russian population, through commercial application of research results. Accordingly, the Ministry of Science and Technology and the Ministry of Education, along with the Russian Academy of Science, is currently embarking on the creation of offices of technology transfer in several universities and academy research institutes, to complement and facilitate interaction with the existing network of research parks, patent offices and other centres. Additionally, new educational programmes have been created to establish certification for professionals in the field of 'Management of Innovation', led by the Russian State University of Innovation Technology and Entrepreneurship in Moscow.

Conclusion

Since 1992, the Government has sought to adopt legislation to bring the IPR laws of the country on a par with international standards, with a view to ultimate admission of the Russian Federation to the World Trade Organization. More significantly, the Government currently is very actively engaged in revising IPR laws to address international standards, such as the amendments to the trademark law in December 2002 and important amendments to the patent law in March 2003. At the same time, the development of new initiatives to promote the transfer of the research results of universities and research institutes to commercial application, and to create networks of skilled technology transfer professionals, holds great promise. Collectively, these developments are extremely encouraging. Undoubtedly, the greatest need for improvement now in the Russian Federation is the strengthening of the country's judicial systems, experiences and practices for the enforcement of its IPR laws.

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Andean Pact Countries of Latin America

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Introduction

The Andean Pact, or Pact of Cartagena (Acuerdo de Cartagena), named after the place where the treaty was signed, was created in 1969 and initially comprised Bolivia, Colombia, Chile, Ecuador and Peru. Venezuela joined in 1973 and Chile left in 1976. In 1997 it changed to the Andean Community. Its stated objective is the balanced and harmonious development of its member countries through political and economic integration. Towards this end, its most important instruments are the harmonization of economic and social policies, common industrial policies, liberalization of trade within the Community, a common external tariff and communication infrastructure development (CAN, 2002a).

The maximum political authority of the Andean Community is the Commission, formed by national representatives. It normally meets three times a year and its decisions are numbered sequentially and have the force of law in each member country. Its technical and executive body is the General Secretariat, supported by an administrative and technical office located in Lima, Peru. Additional important structures within the Andean Pact framework are the Andean Parliament and Court and the Andean Finance Corporation (Corporacion Andina de Fomento), among others (CAN, 2002a).

The Andean Pact was initially launched as a political and economic development mechanism through economic integration. However, each country sought to develop a local industry using tariff and other barriers to protect it in its initial 'juvenile' phase. Governments intervened heav-

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ily in the economy through planning and direct investment. This contradiction led to a progressive slowing down and paralysis of the initially dynamic Andean Pact.

In its first 20 years of existence the Pact was not able to implement any of its ambitious integration programmes on a significant scale. The most difficult proposition was the establishment of common industrial policies in key sectors, such as the car industry, aimed at coordinated and complementary industrial capabilities. Thus, the manufacture of specific types of cars and components were assigned to different countries. After years of acrimonious negotiations, these attempts were abandoned in the 1980s.

Intraregional trade grew modestly in the 1970s, increasing from 2.1% of the total foreign trade of the Andean countries in 1970 to 4.6% in 1979. The economic crisis of the 1980s affected each member country's integration efforts. The initial response to the crisis produced a first generation of structural adjustment programmes, which had an important impact on trade and, in particular, on intraregional trade, which declined by about 40% and then stagnated (IFEDEC, 1987).

Later, the new paradigm of open economies and free trade took hold in all Andean Pact countries, producing a reassessment and reorientation of the regional economic integration efforts. The key event was the bilateral decision of Colombia and Venezuela, made in 1989, to completely liberalize their trade within a year. This produced an important revitalization of the Andean Pact; this time basically centred on intraregional free trade and the establishment of a common external tariff. Trade within the member countries grew exponentially and reached about US$5.7 billion per year in 2001 (CAN, 2002a). Trade is now essentially free between Colombia, Venezuela, Ecuador and Bolivia; with Peru opening up more slowly. Cross-investment, principally between Venezuela and Colombia, has increased hugely. Many local companies have set up subsidiaries in neighbouring countries. This success has also dynamized other areas within the Andean Community, one being the enactment of trade-related regional legislation.

Development of Intellectual Property Rights Protection in the Andean Community Countries

The most representative policy of the Andean Community in its first period of existence was the famous Decision 24 of December 1970, which established a common regime for the treatment of foreign capital and brands, patents, licences and royalties (JUNAC, 1982). It heavily regulated foreign investment in the member countries, providing strong support to national capital. Whole economic sectors like financial services and banking, for example, were reserved for national capital. Foreign investment as well as capital export had to be authorized by government. The progressive conversion of foreign companies into national ones was foreseen.

The widely held perception of abuses in the licensing of foreign technology to local companies also led to standards designed to strengthen the bargaining position of national companies in relation to foreign providers of technology. Licences had to be approved by government and had to conform to certain standards. Restrictions for the licensee on use of the technology and of the products manufactured with it were forbidden. Member countries were instructed to set up specialized intellectual property (IP) offices.

In 1974 standards for granting and managing patents and brands were established through Decision 85 (JUNAC, 1982). This decision developed the basic tenets of Decision 24 in the area of IP. Patentability requirements and administrative procedures to grant them were defined. The protection granted was generally weak, in response to the idea that this system benefited basically foreign companies. The period of patent protection was, for example, 10 years and strong compulsory licensing possibilities were established.

In the current open-economy phase of the Andean Community, Decision 24 and its related norms were abandoned and substituted by new regulations allowing foreign investments and international movement of capital. In the area of IP, stronger protection of patents and brands was provided, and new areas, such as industrial secrets and denominations of origin, were opened. This new trend started with Decision 311 in 1991 and Decision 313 in 1992, followed by Decision 344 in 1993 and Decision 489 in 2000. This last one adjusts the Community norms to the requirements of the Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement of the Uruguay Round of the World Trade Organization, making the Andean Community the first subregional group to comply with them (ALADI, 2000). As a result, the IP regime of the Andean Community countries conforms closely to standard international practice (SELA, 1994; ALADI, 2000).

The current intellectual property rights (IPR) policy of the Andean Community countries includes a common patent and plant breeders' rights (PBR) system, expressed in Decisions 486 and 345. A common policy regulating access to genetic resources, which has IPR implications, was approved in 1996. It is contained in Decision 391.

The Andean patent regime, defined by Decision 486, follows closely the World Intellectual Property Organization (WIPO) and TRIPS directives. It permits the patenting of all products or processes in all fields of technology if they are new, inventive and can be applied industrially. Plant and animal species and the biological procedures needed to obtain them are explicitly excluded, together with certain other categories. Microorganisms can be patented. Inventions related to living beings and materials must be deposited in an institution authorized by the national authorities and must include materials that will be part of the description of the patent document.

Decision 345 establishes a common PBR system based on the International Union for the Protection of New Varieties of Plants (UPOV) model, taking an intermediate position between the 1978 and 1991 conventions. Thus, for example, the concept of essentially derived varieties is included.

The supranational legislation is applied in each country. In the case of Decision 345, national by-laws are required. The status of the actions taken by the member countries in this regard as at December 2001 is presented in Table 15.1. The validity of the supranational legislation in the member countries has been challenged in the courts, which have until now upheld it. For example, several rulings by the Venezuelan Supreme Court have tacitly recognized the validity of Decision 344.

Description of Intellectual Property Rights Related to Agriculture in the Andean Community Countries

Plant breeders' rights

The IPR legislation most directly related to agriculture is the PBR system. In the case of the Andean group, its principal objective is to recognize and guarantee the protection of PBR over new plant varieties through the issuing of a certificate valid in all member countries. Decision 344 considers that a breeder has created a new variety when he/she has applied scientific knowledge to obtain a homogeneous, distinct and stable variety and when he/she has given it a generic denomination (CAN, 2002b). Only varieties created that satisfy these criteria can be protected, i.e. discoveries are excluded. This gives exclusive rights to the creators for a period of 15–25 years depending on the species. The breeder has to deposit a living sample of the variety.

Decision 345 makes it possible to extend the rights to essentially derived varieties. A variety is considered to be essentially derived when, although distinguishable from other varieties, it is predominantly

Table 15.1. National by-laws of Decision 345 of the Andean Community (status as of December 2001).

Country, official act and date
Bolivia Secretarial Resolution No. 064/96, 1996 and Administrative Resolution RA UC/PNS006/97, 1997
Colombia Decree No. 533, March 1994
Ecuador Executive Decree 3708, April 1996 and Intellectual Property Law, May 1998
Peru Supreme Decree 008–96-ITINCI, May 1996
Venezuela Presidential Decree 3136, December 1998

derived from another variety and also retains essential characteristics, which result from the genotype of that other variety. Therefore, the breeder is not harmed by whoever reserves and plants, for his/her own use or to sell as prime material or food, the product obtained from the cultivation. Exceptions include the commercial use of multiplication, reproduction and propagation materials, including whole plants and their parts, of fruit, ornamental and forestry species.

The breeder will have provisional protection dating from the presentation of the claim to the granting of the certificate. The Decision also gives priority rights over any other request, during a 12-month period, seeking the protection of the same variety in any other Andean Community country. The certificate holder grants licences for the protected variety.

Decision 345 permits the use of protected varieties for non-commercial purposes, for experimental uses and for developing new varieties. Its implementation in each country requires a national by-law, which has been enacted in all member countries. As established in the Decision, each member country has to create a national registry of protected plant varieties.

Additionally, the Community is instructed to maintain a regional registry of protected varieties. This registry is governed by a Regional Committee for the Protection of Plant Varieties. This body: (i) harmonizes procedures, laboratory tests, deposits and cultivation of samples necessary for the registration of a variety; (ii) defines technical criteria for distinguishing between varieties, so as to determine the minimum number of characters that have to change to be able to determine whether a variety is different from another; (iii) analyses matters related to the protection of essentially derived varieties; and (iv) proposes norms for the Andean Community.

Bolivia, Colombia and Ecuador are party to UPOV, all to the 1978 Act, since 1999, 1996 and 1997, respectively (UPOV, 2002). Bolivia and Colombia are the countries with more protected varieties. Colombia has issued (as of October 2002) a total of 390 certificates, 362 of them for flower varieties (A.L. Díaz, ICA, Colombia, personal communication).

Access to genetic resources

As early as 1993, in Decision 345 on PBR, the Andean Community countries declared their intent to regulate access to genetic resources. This led to the approval in July 1996 of Decision 391. In this way, a link between PBR and access to genetic resources was established.

Decision 391 essentially creates a system for authorizing the access and use of native genetic resources. National authorities will contract with interested parties regulating the conditions of access and use of genetic

resources, including the sharing of benefits (CAN, 2002b). An Andean Committee of Genetic Resources will serve as an information clearing house, technical advisory and harmonizing body for the authorization process. No IPR on genetic resources and products derived from them will be recognized if the access to them does not conform to this Decision.

Decision 391 has been implemented in all member countries. Bolivia and Venezuela have enacted special laws or by-laws developing Decision 391.

The actual practice of granting access to genetic resources is still incipient. Only Venezuela has had a significant number of requests, 20 as of July 2001 (Vivas, 2001). Almost all requests in all countries are from universities and research centres. Their processing has been very slow and cumbersome, because of legal uncertainties and complicated norms.

The definition of genetic resources adopted in this decision ('all biological material which contains genetic information of real or potential value') includes plant varieties. Therefore, the potential for overlap and conflict between access to genetic resources and PBR exists.

The Andean Community countries adopted in July 2002 a Regional Biodiversity Strategy, within the stipulations of the Biodiversity Treaty.

There have been at least seven cases of alleged 'biopiracy' in Andean Community countries, denounced by international and national non-governmental organizations (NGOs) interested in protecting biodiversity. This has led agricultural research centres of the Consultative Group on International Agricultural Research (CGIAR) located in the region to contest in developed countries, together with some of these NGOs, some patent applications on local plant species or varieties (Revista del Sur, 2001).

Impact of Intellectual Property Rights on Agriculture in the Andean Pact Countries

The rapid privatization of biological technologies traditionally mostly in the public domain, brought about by the development of biotechnology, has increased the importance of IPR in many sectors, particularly in agriculture. Special IPR systems for agriculture, i.e. PBR, are increasingly complemented by the application and use of more traditional ones, such as patents. But many political and practical issues remain to be solved for an extensive and effective protection of IPR in this sector.

Theoretically, IPR could impact on agriculture in several ways (Jaffé and van Wijk, 1995). The first and most direct way would be the acceleration of the rate of technologic innovation in agriculture, which is, after all, the economic justification of an IPR system. This could occur both in agricultural practices directly, or indirectly in industries that produce

inputs for or process prime materials from agriculture. The basic condition is that technologies could be protected effectively. Changes in research and development investments and distributions are indirect indicators of trends in this respect.

The structure of agricultural production could also be affected by IPR, if they determine the access to and use of technologies. Differences in the prices and costs of protected or unprotected technologies, which have an effect on the competitiveness of different production systems or industries depending on the scale of production, could favour certain systems or industries over others. The most common worry here is the perceived negative effects of IPR on traditional, small-scale production systems.

Finally, IPR in agriculture could have an impact on the relationship of this sector with others. One possibility would be a strengthening of agriculture against consumers for example, i.e. an increase in the cost of agricultural products for consumers.

In general, Andean Community countries have weak local or national innovation systems. Particularly in agricultural industries where technologies can be protected, there are only very limited local capabilities for generating technologies. This means that IPR in these countries will be more important for the international access to needed technologies and products than for the stimulation of local technological innovation (van Wijk and Jaffé, 1996). A good example of this is the case of the flower industry in Colombia. This industry, which in the last 20 years has grown into one of the most important worldwide, has an international reputation of not respecting IPR of flower varieties. Threats of punitive restrictions to access markets, principally the crucial American market, was the most important reason for the relatively rapid enactment of Decision 345, a legislative track that was perceived as easier than a national law. This generated a conflict between the defenders of PBR in Colombia, the flower and seed industry, the Trade Ministry, Congress, non-governmental organizations and some political parties, which were in favour of a national, much more restrictive, law.

Plant breeding has been mainly a public sector activity in the Andean Community countries and is concentrated in the National Agricultural Research Institutes (NARIs) of each country, as well as in the two international centres located in Colombia and Peru. The most important programmes have been in maize, rice, sorghum, potatoes, sugarcane and beans. Some breeding has also been done by universities. In general, breeding consists of adapting foreign materials, commonly from the international centres in the case of food crops, to local conditions through backcrossing. The only significant private breeding activity is that carried out by coffee growers in Colombia. Some local industries have had limited experience in adaptive breeding of specific crops, like the example of sorghum in Venezuela and sugarcane in Colombia. It is to

be expected that the existence of PBR, coupled with effective enforcement, should stimulate the investment of private companies in plant breeding.

Most of the seed industry in the Andean Community countries relies on foundation seed produced by the NARIs to reproduce and commercialize. The public sector varieties, until the recent approval of the PBR system, were inadequately protected so that the NARIs could not profit from them. The enforcement of PBR could result in an important source of revenues for these institutes, as the experience of Argentina shows (Jaffé and van Wijk, 1995). In the present context of strong budgetary restrictions, which all these institutions face, this could be an important element in their future prospects and roles.

Multinational seed companies have had a strong, and in many cases dominant, presence in the Andean group countries for many years. In particular, the larger markets of Colombia and Venezuela have been attractive for hybrid maize, sorghum, cotton and vegetable seed companies. They generally carry out only adaptive breeding, if any, in the host countries. The lack, until recently, of adequate IPR protection in the Andean group countries has not been a factor in the decision to locate seed production facilities in these countries. Market size and general business climate are generally the determining reasons for these decisions. On the other hand, these companies usually deal with hybrids, which generally do not need legal IPR protection.

IPR related to agriculture, and specifically PBR, have not been in place for long enough to have had any real impact on agriculture in the Andean Community countries. No effective enforcement structures existed until December 1996, given that some of the countries have only advanced as far as the enactment of legislative measures and the setting up of public sector organizations to manage and enforce them. However, as the experience of Argentina clearly shows, effective enforcement of PBR requires that breeders organize themselves to this end, and this has not yet happened in any of the Andean Community countries.

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Costa Rica

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Introduction to Intellectual Property Rights

In Costa Rica, intellectual property rights (IPR) are protected in the Constitution. Article 47 of the Constitution establishes that, according to law, every author, inventor or producer will be granted a temporary, exclusive right in his or her creation, invention, trademark and commercial name. Based on that promulgation, Costa Rica has implemented a series of laws and subscribed to many international conventions related to IPR protection (Palacios and Salazar, 1995). The rights that are protected include patents, utility models, industrial models and designs, trademarks, commercial names, denomination of origin and copyrights. IPR laws in Costa Rica are very strong and are on a par with human rights. In the field of industrial property, Costa Rican IPR laws regulate patents, models and industrial designs, utility models, trademarks, commercial names and slogans. The Patent Law dates from 1983 but has been recently amended. Other important laws related to IPR include the Trademark Protection Law and the Law for Special Procedures for the Enforcement of IPR.

Costa Rica is a member of the World Intellectual Property Organization (WIPO) from whom it continuously receives technical assistance and training. The country is also a member of the 1916 Buenos Aires Convention and, very recently, the Paris Convention and the Patent Cooperation Treaty. Trademarks are protected in Costa Rica by the Trademark and Other Distinctive Signs Law. Trade secrets are protected by the Law for Undisclosed Information. The 1982 Copyright Law has also undergone many changes and reforms, most implemented under the Bern Convention, Geneva Convention, Rome Convention and the

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Phonogram Convention. More recently the country approved the WIPO 1996 treaties in the field of phonograms. Costa Rican intellectual property (IP) laws are summarized in Table 16.1.

Piracy is not, and never has been, a great problem in Costa Rica (R. Sherwood, 1996, personal communication) even though the Patent Law and the Copyright Law were promulgated only 15 years ago. After Costa Rica signed the General Agreement on Tariffs and Trade or GATT (now the World Trade Organization (WTO)), the country recognized that substantial changes were needed in the existing IPR laws.

Current Intellectual Property Rights

Patents

The Costa Rican patent system is very different from the US patent system. Unlike the USA's right to exclude others from using the patented invention system, the Costa Rican patent owner is granted a double right

Table 16.1. Costa Rican intellectual property system.

Category	Components
General	Constitution
	Law for Special Procedures for the Enforcement of IPR
International Conventions	Paris Convention
	Bern Convention
	Buenos Aires Convention (1910)
	Washington Convention (1946)
	Geneva Convention (1952)
	Rome Convention (1961)
	Geneva Convention (1971)
	WIPO Treaties for the Protection of Phonograms (1996)
International Agreements	Uruguay Round, GATT (WTO)
	Free Trade Agreements Costa Rica–Mexico (1994)
	Central America – Dominican Republic (1999)
Industrial Property	Patent, Utility Models, Industrial Models and Designs Law
	Regulations to the Patent Law
	Trademark Protection Law
	Regulations to the Trademark Protection Law
	Seeds Law
	Wildlife Conservation Law
	Biodiversity Law
	Trade Secret Protection Law
	Integrated Circuits Protection Law
Copyright	Copyright Law
	Regulations to the Copyright Law

– the right to exclusively exploit the patent and give licences to third parties, and the right to exclude others. The right to exclude others was incorporated into the law in the recent amendments to comply with the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), including Trade in Counterfeit Goods. An invention is any creation of human intellect capable of being applied in industry and fulfilling the patentability requirements. It can be a product, a machine, a tool or a process. It is important to mention that Costa Rican law excludes some inventions or fields from patentable subject matter. These exclusions are: discoveries, scientific theories, mathematical methods and software by itself. Aesthetic and literary works are also excluded, as are plant varieties (which get special protection by other laws), animals and the biological processes used to obtain them, plans and principles, economic or business methods, original methods, intellectual activities, game rules, therapeutic and surgical methods, methods of diagnosis applicable to human beings and animals, and inventions contrary to public health, security, public order and morals.

In accordance with the usual patenting principles, the three requisites for patentability are novelty, non-obviousness and utility. The patent term is for 20 years from the filing date in the country of origin. Due to an error, no reference to national applications was made in terms of the beginning of the term. Other important characteristics of the Costa Rican patent system are:

- the obligation to exploit the invention in Costa Rica within 3 years of the date of issue;
- compulsory licensing in special cases (as an anti-competitive measure, in the case of dependent patents, or in the case of public need);
- patent examinations are not made by the Registry but by professionals from professional associations and universities;
- 'first-to-file' system, with publication after fulfilling the formality examination;
- a pre-grant opposition system after publication; and
- no maintenance fees.

Costa Rican law also recognizes utility models or petty patents. Utility model protection is given to certain inventions that do not meet entirely the requirement of novelty. This kind of protection is especially given to any new disposition of form obtained or introduced in tools, work instruments or known utensils that allows a better function or a special function.

Designs are also protected by the Patent Law. The law uses the terms 'industrial model' to refer to any plastic form associated or not with lines and colours giving a special appearance to a product or craft work and that can be used for its production. 'Industrial designs' are defined as any group of lines and colours giving a special appearance to a product. Novelty is required and the period of protection is 10 years.

Copyrights

Costa Rican Copyright Law is very similar to laws in other countries. Protection is given to the form of expression of original ideas. All artistic and literary works are protected including books, pictures, architecture, sculpture, etc. Software programs are protected under the Copyright Law. Costa Rica recognizes moral, patrimonial rights and neighbouring rights. The term of protection is the author's life plus 70 years after the author's death. Infringement of copyrights in Costa Rica is penalized with imprisonment. Registration is not necessary to acquire the right, but there is a Registry of Copyright in which, through a very simple and inexpensive process, an author can register his/her right.

Trademarks

In Costa Rica a trademark can be any sign or combination of signs that can distinguish goods and services. It can also be words or a group of words, letters, numbers, figurative elements, monograms, lines or a combination of colours. It can also be in the form of the products, wraps or bottles, packaging, etc. The first one to use the trademark bona fide in commerce has preference for registration, but if it is a new trademark or it has been in commerce for less than 3 months the system is a 'first-to-file' system. If there is a dispute over the previous use of the trademark it will be solved with the date of presentation. Those things that cannot be considered a trademark include, among others, generic or common names, names against moral or public order, isolated colours, numbers or digits (except when they are presented in a distinctive and unique way), national emblems, etc. There are other inadmissible trademarks for better rights of third parties such as if the sign is identical or similar, or susceptible of causing confusion, to a registered trademark or in the process of being registered, well-known trademarks, trademarks referring to persons not being the applicant, etc. The applicant has to submit an application with all the requirements and a formal and substantial examination is carried out. After both examinations, a publication is made. After publication there is an opposition period of 2 months. The previous use of an identical or similar registered trademark can prevent registration. The term of protection is 10 years and is renewable. A registered trademark gives the owner the right to exclude others from using, without consent, identical or similar trademarks in identical or similar goods and services. Trademark licensing contracts have to be registered at the Trademark Office. The Trademark Office can cancel a licensing contract if someone with legitimate interest requests this be done on the grounds of quality control defects. A trademark can also be cancelled for non-use after 5

years of registration. Other types of trademarks mentioned in the law are: certification trademarks, collective trademarks, commercial names, and emblems and slogans. Costa Rica also gives protection to geographical indications and denominations of origin.

Plant variety protection

Plants, animals and biological processes are not patentable in Costa Rica, but there is a regulation in the Seeds Law that establishes that the Seeds Office has the obligation to create a protected variety registry and establish procedures that control plant breeders' rights. It seems that, when drafting this law, Costa Rica received collaboration from Spanish consultants who influenced the regulation. However, at this moment there is no plant variety protection in Costa Rica.

Since the late 1990s, the Seeds Office has been working on the possibility of creating regulations needed to protect plant varieties using a system in accordance with the International Union for the Protection of New Varieties of Plants (UPOV). The draft is already in Congress and is subject to considerable analysis and consultation. A political decision on this matter was made when Congress stated in the Patent Law that plant varieties will be protected by a special law. What remains to be decided is whether Costa Rica will join UPOV. As mentioned, the draft was made to fulfil UPOV requirements, but it does not specifically state that Costa Rica will become a UPOV member. The problem is that this project has received a lot of criticism from certain sectors, especially non-governmental organizations representing farmers and indigenous people.

Traditional knowledge

Protection of traditional knowledge has been widely debated (UIGN and ICTSD, 2002). The need to protect traditional knowledge has been also recognized in recent years, although it has also been recognized that the holders of such types of knowledge considered incomprehensible and even contrary to their own beliefs the possibility of a certain kind of protection of such knowledge. One reason for the need for protection is directly related to the provisions allowing protection of life forms by patents. With the possibility of persons and companies accessing genetic and biological resources, mainly from developing countries, and then being granted patents over inventions derived from those resources, an unfair situation has emerged. Developing countries, based on the Convention for Biodiversity, now want to be recognized for their contribution to this process and the protection of traditional knowledge is one way to do this.

Reference to traditional knowledge includes knowledge associated with the use and preservation of species and biological and genetic resources. This information is in the hands of local and indigenous communities, which have contributed enormously to the improvement of the agricultural and pharmaceutical sectors. IPR as known today are not an adequate means of protection of traditional knowledge due to its unique characteristics. Different approaches, such as comparing traditional knowledge with folklore, have been attempted without success. In order to protect knowledge and expressions of these communities a new *sui generis* regime has to be created. One example of such intention is Decision 391 of the Andean Community, which expressly recognizes the traditional knowledge of local communities. In Costa Rica, the Biodiversity Law, under the name '*Sui Generis* Intellectual Community Rights', recognizes the knowledge, practices and innovations of the local and indigenous communities, related to the use of elements of biodiversity and associated knowledge as rights of the local and indigenous communities. This right exists and it is legally recognized by the sole existence of the cultural practice or the associated knowledge to a certain biochemical or genetic element; it does not require previous declaration, express recognition or registration. This recognition implies that these rights will not be affected by any form of IPR granted through local and international laws. The specific nature and scope of the rights and their requirements will be determined by consultations with local and indigenous communities. It is important to note that the Biodiversity Law requires that any kind of protection, especially by patents, to biochemical or genetic elements should be authorized by a specific Commission within the Ministry of Environment and Energy. This Commission can reject the application for protection if it is related to a *sui generis* intellectual community right.

Trade secrets

The objectives of the Law for Protection of Undisclosed Information are to protect undisclosed information related to trade and commercial secrets and to contribute to the promotion of technological innovation and dissemination and transfer of technology. The requirements for protection are secrecy or confidentiality, that the information has to be legally under the control of the owner adopting measures to keep it secret and that the information has to have commercial value to remain secret.

Changes that have Occurred in Intellectual Property Rights Laws During the Past 5 Years

As in most developing countries, IPR protection has never been well known or studied much in Costa Rica. Until the 1980s, IPR laws dated

from the last century. The laws were there but no one enforced them. However, inspired by a critical movement in the 1970s, the situation changed in the 1980s. Big changes were also made in most Latin American countries' IPR systems – especially with regard to patents. Studies and papers began to criticize the distortions and problems associated with patents produced in Latin American economies (SELA, 1988). This situation continued in Latin America before and during the GATT negotiations. Some of the characteristics of these systems included: (i) weak protection in some fields and a lack of protection in others, with the latter especially found in pharmaceutical patents and agrochemical areas; (ii) short patent terms; and (iii) lack of IPR enforcement.

The situation changed greatly after the announcement of the TRIPS Agreement. Many Latin American countries, including Costa Rica, soon became members of the WTO and had to modify their existing IPR laws. Even today, there is debate as to the real reasons why these laws were changed.

There has not been a real and detailed debate on IPR protection in Costa Rica. Most of the changes in the laws are not the result of studies or debates, but, instead, are in response to specific demands from the international community. In a global economy with open markets and free trade agreements, IPR rules will also have to be changed so that a country can remain competitive (Sherwood, 1990). Unfortunately, in Costa Rica these changes have been made without considering the impact, positive or negative, of those changes on the country's socio-economic development. Neither has the need for an integral approach of the issues been considered in which other policies, like promoting better education, giving incentives to innovation, research and development, etc., may be needed along with an IP system so that the country can benefit from it. With clear rules now articulated under TRIPS and with no possibility of reverting back to the old laws, Costa Rica should realize that IPR systems must be conceived in accordance with a chosen economic development model. Unfortunately, Costa Rica is making only patchwork changes, which reflect neither a policy nor a strategy for the social and economic development of the country.

Since Costa Rica became a WTO member in 1994, the Government became aware of the changes needed to comply with TRIPS requirements.

The first big challenge for the Costa Rican IP system was to amend laws in accordance with TRIPS requirements. In terms of patents, this meant basically allowing patentable subject matter to include microorganisms and microbiological processes with protection for plant varieties. Compulsory licences also needed amendments as required by TRIPS. However, the most relevant change was amending the patent protection period from a 12-year period or a 1-year period in case of pharmaceuticals, agrochemicals and food, to a 20-year period. This has had a substantial impact on pharmaceutical, agrochemical, fertilizer and food and beverage industries.

Pending and Proposed Changes in Intellectual Property Rights

As well as facing the challenge of implementing TRIPS, the Central American region and all 'American' countries will have to address IPR issues in negotiations to create the Free Trade of the Americas region by the year 2005. Another area of negotiation where IPR will be very important is in the negotiation of a free trade agreement between the USA and Central America. Other pending changes in the IPR laws are related to modifications needed in order to correct some technical or spelling errors in the laws.

Conditions Unique to Costa Rica

Traditionally, agriculture has been an important sector in Costa Rica. Besides tourism, which is the country's main income, the Costa Rican economy is based on two main export products: coffee and bananas. The coffee farms are mostly medium sized or small, in contrast to banana production, which is owned by transnational companies with large fields. Agriculture is a fundamental area in the social and economic development of the country. The authorities are reluctant to protect these industries with patents, products and processes related to agriculture due to the lack of study on the impact this can have in this sector, especially with regard to price increases. Costa Rica is not alone in facing these concerns. There is currently a worldwide debate about the convenience of strong IP regimes in developing countries (IPR Commission, 2002).

Despite these problems, Costa Rica has a large number of researchers working on improvement of plant varieties, including transgenic materials. The country's efforts in this field are well recognized in Latin America, due to the high level of human resources and research facilities (Ramírez, *et al.*, 1996). Moreover, many of these researchers were the first to point out the consequences of not protecting the products of their research activities. Costa Rican farmers use imported seed for some crops and domestic seeds for others. For coffee production, the country grows its own seed and there is a public research system that provides growers with wide access to new varieties and technologies. Because banana production is in the hands of transnational companies, these companies have their own research system, which transfers technologies to all their small, commercial producers.

There are a number of small, successful companies involved in tissue culture and micropropagation. Costa Rica has the potential to benefit from biotechnology, especially from agricultural biotechnology. In addition, Costa Rica is a privileged country in terms of biodiversity and genetic resources, the raw materials for biotechnology (Salazar, 1992, 1996). These are the facts that have to be taken into account when making decisions regarding IPR protection in agriculture. As mentioned

when dealing with the question of protecting agricultural biotechnology in developing countries like Costa Rica, some concerns arise. Developing countries want to ensure their access to technology. Technology transfer is a key issue (Jorda, 1995). Developing countries are aware that innovation is crucial for development and that protection of IP is a basic step. However, they also do not want their farmers to pay high prices and limit their access to agricultural goods. Thus, the decision is a difficult one (Salazar, 1995).

Costa Rica is rich in biodiversity. This gives the country a special opportunity in terms of development. Traditionally, biodiversity was considered a natural resource, the heritage of humankind. Ironically, with the development of biotechnology and the possibility of protecting biotechnological inventions with exclusive rights, large differences between developed and developing countries have arisen, because biodiversity is considered a raw material for the development of biotechnological products. It is well known that geographical distribution of biodiversity is very uneven, with underdeveloped countries generally having the greatest diversity. The products derived from developing countries' biodiversity are transformed and patented in industrialized countries. The goods may have high commercial value and are sold and distributed without any compensation being paid to the country of origin. Following lengthy debate, most countries have now subscribed to the Biodiversity Convention (Asebey, 1996), which establishes the sole sovereignty of each state over its own biodiversity. Inspired by this idea, there is a Wildlife Conservation Law in Costa Rica that establishes that biodiversity is in the public domain and of public interest. All wildlife is part of the national wealth, and any exploitation of the national biodiversity, such as extraction, production, commercialization, industrialization and use of genetic materials, is subject to the Ministry of Environment's authorization.

To improve the biodiversity-related legislation, the Biodiversity Law was enacted in 1998. Costa Rica is one of the first countries in the world to have a law of this type and to implement the possibilities achieved by developing countries in the Biodiversity Convention. In conformity with articles 62 and 69 of the Law, every research programme or bioprospecting on genetic material carried out in Costa Rican territory requires access permission, unless covered by one of the exceptions foreseen by the law.

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European Union

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Introduction

For more than 20 years it has been a matter of dispute whether plants can be the subject of patent protection, in addition to or as an alternative to the protection afforded by plant variety rights. This was one of many questions in patent law to which no single global answer could be given, owing to the differences of law from one country to another.

Under the laws of the USA and Australia, for example, a clear affirmative statement can be made, subject of course to meeting the basic conditions of patentability that apply to any invention. But in Europe and most other countries it has been more difficult to answer this question clearly and simply.

In the previous edition of this book the present chapter focused primarily on the interface between the law of the European Patent Convention (EPC) and the laws of plant variety rights typified by the International Convention for the Protection of New Plant Varieties (UPOV). The European Patent Office (EPO), as the principal representative of official patent opinion throughout Europe, had long been engaged in determining the effect of EPC Article 53(b) on this issue. The relevant portion of this article states that:

> European patents shall not be granted in respect of … plant or animal varieties or essentially biological processes for the production of plants or animals …

In tracing the development of the EPC case law on this subject, the previous chapter reported the refusal by the EPO Board of Appeal of a patent claim to certain genetically modified herbicide-resistant plants on

 Intellectual Property Rights in Agricultural Biotechnology. Second Edition (eds F.H. Erbisch and K.M. Maredia)

the ground that this claim 'embraced plant varieties' and was therefore contrary to EPC law. The chapter concluded with the hope that a test case would be brought to overturn this decision. This has now been achieved. The previous case history is nevertheless important to see this development in perspective and, therefore, an updated version of this is given below.

The European and International Legal Background

Plant and animal varieties

In Europe the patent law was originally considered unsuitable for protecting new plant varieties developed by traditional breeding methods. Special national laws of plant breeders' rights (also called plant variety rights) were therefore established in the 1960s in some countries and an international convention, the International Union for the Protection of New Varieties of Plant (UPOV, 1961), was formed.

Because plant breeders' rights were a major innovation, and to an extent controversial in agricultural circles, they were consciously designed to provide a form of protection less strong than that of patents. For example, two freedoms were enshrined in the law, one express, the other implied. First, it was expressly stated that breeders were free to use a legally protected variety as a starting point for breeding further varieties, i.e. they could do so without payment of a royalty. This was known as the 'breeder's privilege' or 'research exemption'. Secondly, because the rights were restricted to commercial dealing in the reproductive material of the variety, a farmer sowing purchased seed of the variety was implicitly free to save seed from the harvest for subsequent sowing on his own farm. This was the 'farmer's privilege'.

Plant breeders' rights have been highly successful in their own sphere. However, it is now generally recognized that patent law is better suited to the protection of recombinant methods for producing transgenic plants and the resulting products. Patents of this type, claiming methods and products *per se*, have been granted by the EPO.

Animal breeds produced by traditional methods have no legal system for their protection comparable with plant breeders' rights. Following the declaration by the US Commissioner of Patents in 1987 that US patents would be granted for 'non-naturally occurring non-human multicellular living organisms including animals', the first transgenic animal patent was issued in 1988 to Harvard University with claims covering the 'onco-mouse'. After initial reluctance by the EPO to grant the corresponding European patent (and a successful appeal to the Appeal Board), the European patent was issued. This is still under formal opposition by anti-vivisection and animal rights groups.

European patent laws

All European countries have their own national patent law and most are also members of the regional patent system of the European Patent Convention (EPC, 1973). Under the EPC, a single patent application can cover all, or any selection, of the countries that have joined this Convention. EPC law takes precedence over national laws and these are required to be in harmony with it.

In addition there is the politico-economic grouping of the European Community or Union (EU), which can legislate for EU members by Directives or Regulations. Examples are the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (EU, 1998), and the European Council Regulation on a Community-wide system of plant variety rights (European Council, 1994). Most European countries have national laws of plant variety protection and are also members of UPOV. UPOV has been revised more than once since its inception. The previous operative text was the 1978 version (UPOV, 1978). A further significant revision was made in 1991 (UPOV, 1991) and has now been ratified by many member states. This complex mix of applicable laws gives rise to the legal interface problem.

The interface between patent and variety protection

This question has been addressed jointly by the World Intellectual Property Organization (WIPO) and by UPOV in order to determine whether the patent system and the plant variety rights system are incompatible or complementary, each operating in a defined sphere (WIPO/UPOV, 1990). The question is important to patent law owing to the exclusion of plant and animal varieties from patent protection in some countries. For example, as stated above, Article 53(b) of the EPC prohibits patents for 'plant or animal varieties or essentially biological processes for the production of plants or animals: this provision does not apply to microbiological processes or the products thereof'. National patent laws in European countries contain the same provision.

It is noteworthy that the second half of Article 53(b) limits the exclusion. It is believed that this was included to safeguard the patentability of microbial cultivation methods and resulting products, e.g. antibiotics.

The term 'essentially biological' has not yet been judicially defined, although, as mentioned later, some attempt at clarification has been made in the EPC case law. Bearing in mind the birth of the UPOV legislation and the desire to ensure that patents would not impinge on plant breeding methods, the term may have been simply intended to apply to the traditional processes used to breed new plant varieties. In spite of the confusion to which this term has given rise, the legislators seem unable or unwilling to dispense with it.

What is a plant variety?

First there is a problem of semantics. To the plant scientist the term 'variety' is not a botanical taxon and lacks scientific precision. To plant breeders, the term 'variety' served well for practical purposes and was apparently used rather flexibly, without the need for a rigid definition.

The definition of the plant variety, used in the original 1961 version of the UPOV Convention, in Article 2(2) stated that 'For the purposes of this Convention, the word "variety" applies to any cultivar, clone, line, stock or hybrid which is capable of cultivation and which satisfies the provisions of sub-paragraphs 1(c) and 1(d) of Article 2'. (The cited sub-paragraphs dealt with homogeneity and stability.) According to this definition, then, a variety was whatever satisfied the criteria of distinctness, uniformity and stability and was therefore protectable under the UPOV Convention. This definition was removed when the Convention was revised in 1978.

The above arrangement seemed to work satisfactorily for almost two decades. The UPOV system was protected from any interfacial tension with the patent system by its own prohibition of protection by both forms ('double protection') in Article 2(1), which provided that each member state of the Union might recognize the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member state of the Union whose national law admits protection under both these forms may provide only one of them for any given botanical species or genus.

This restriction was reinforced in the patent laws of those countries that had expressly excluded plant varieties from patent protection, e.g. according to the prototype provision of EPC Article 53(b). Since the EPC came into being, very few attempts have been made to disturb the situation by filing patent applications for plant varieties as such.

The Early EPC Case Law on Article 53(b)

In Europe the area excluded from patent protection was identified as coterminous with the area covered by the UPOV system at the time the point arose for decision in the Ciba–Geigy case (Ciba–Geigy, 1984). The claim before the EPO related to 'Propagating material for cultivated plants, treated with an oxime derivative according to [a specified] formula… '

In allowing this claim, the Technical Board of Appeals held that Article 53(b) 'prohibited only the patenting of plants or their propagating material in the genetically fixed form of the plant variety'. With reference to the claim in dispute, the Board observed:

> It is immaterial to the question of patentability that the propagating material which is treated can also be, or is primarily, a plant variety. If plant varieties have been excluded from patent protection because specifically the achievement involved in breeding a new variety is to have its own form of protection, it is perfectly sufficient for the exclusion to be left restricted, in conformity with its wording, to cases in which plants are characterized precisely by the genetically determined peculiarities of their natural phenotype. In this respect there is no conflict between areas reserved for national protection of varieties and the field of application of the EPC. On the other hand, innovations which cannot be given the protection afforded to varieties are still patentable if the general prerequisites are met.

This approach to Article 53(b) was consolidated in the case of Lubrizol Genetics Inc. (Lubrizol, 1990). In the process claimed in this application, parent plants with desired characteristics are selected, test crossed, marked and stored. The hybrids resulting from the crosses are then evaluated for desired traits and phenotypical uniformity, and that pair of parent plants (at least one of which is heterozygous) that provides the desired hybrids is selected. At least the heterozygous parent plant is multiplied by cloning, and the crossing of said pair of parent plants is repeated as often as desired to provide hybrid plants on a large scale. The Technical Board of Appeal considered that, in a multistep process, each single step as such may be characterized as biological in a scientific sense. However, in this case the essence of the claimed process lay in the particular combination of specific steps. The totality and the sequence of the specified operation neither occurred in nature nor corresponded to classical breeders' processes. The arrangement of steps in the claimed process represented an essential modification of known biological and classical breeders' processes, and the efficiency and high yield associated with the product showed important technological character.

The Board held that in Article 53(b) the exclusion of 'essentially biological' processes for the production of plants and animals should be construed narrowly. Whether or not a process is to be considered as 'essentially biological' has to be judged on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the result achieved.

It was also decided that the products of this process could be claimed in 'product-by-process' terms. Such products were not 'plant varieties' and therefore were not excluded as such under the first part of Article 53(b). The conclusion of the Board on this point was based on the fact that the hybrid seeds or plants produced by this process, though phenotypically uniform, would not breed true, i.e. did not possess the degree of stability necessary for them to be classed as varieties. This reasoning must have seemed rather puzzling to the applicant, who

had no doubt that his strategy was in fact to produce 'hybrid varieties' although this term was not emphasized in the specification. Thus, according to the European case law, especially the Ciba–Geigy case, the excluded area was to be equated with that which is protectable under UPOV and corresponding national laws of plant variety protection. Plants that have been specially bred as a new variety were to be protectable by plant breeders' rights if criteria of distinctness, uniformity and stability were met and they were *de facto* excluded from patent protection under patent laws in Europe. This conclusion was seen as conforming to the then-prevailing UPOV ban on double protection for the same entities.

It was therefore the understanding in patent circles that a variety was a subgroup of a plant species (or subspecies) containing individual members that resembled one another phenotypically and complied, for the most part, with a set of listed characteristics that constituted the official description of a protected variety by which it was distinguished from other such subgroups of the same species. Patent law could live comfortably with such a notion. With the advent of plant biotechnology, patent specialists argued that the above exclusions could not apply to recombinant DNA methods and transgenic plants, and, for a time, this view was accepted by the EPO Examining Division. However, the next important case to come before the EPO Board of Appeals resulted in a reversal of this policy. To follow a chronological approach to these developments, further discussion of the patent case law will be postponed until developments in plant variety law have been outlined.

Plant Variety Rights: Legal Developments

Two major developments took place after the above-mentioned patent case law was established, namely, the Revision of the UPOV Convention in 1991 (UPOV, 1991) and the European Commission's Regulation on Community Plant Variety Rights (European Council, 1994).

The European Community Plant Variety Rights

The idea of European Community Plant Variety Rights stemmed from an initiative of the European Community Directorate responsible for agriculture. According to Article 1 of the Regulation, the system is to be established as 'the sole and exclusive form of Community industrial property rights for plant varieties'. A preceding explanatory recital states that the Regulation 'implements the ban on patenting plant varieties only to the extent that the European Patent Convention so requires, i.e. to plant varieties as such'.

The 1991 revision of UPOV

The protection given under UPOV has been improved and strengthened by this revision (Byrne, 1991). The prohibition of double protection in former Article 2 has been removed, although member states retain the power to preserve this prohibition in their national laws.

A carefully worded definition of a plant variety now stands at the forefront of this Convention in Article 1 (vi). It states: 'variety' means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be:

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes;
- distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
- considered as a unit with regard to its suitability for being propagated unchanged.

UPOV spokesmen insisted that a definition conforming to the usage of the term in the agricultural industry was essential in present-day circumstances. The new definition is no longer to be equated with 'UPOV – protectable variety'.

Another respect in which protection under UPOV has been widened is that, under Article 14 (Scope of the Breeder's Right), the right is to extend to 'essentially derived varieties'. The complex definition of this term given in Article 14(5) will not be discussed here (see Byrne, 1991). However, the Vice-Secretary of UPOV has declared the view that it would cover a genetically modified variety that retains the whole genome of the original protected variety.

The freedom for breeders, farmers and for research

Freedoms for breeders and farmers are seen by some (mainly those opposed to intellectual property) as threatened by intellectual property systems, especially by patents on transgenic plants and animals.

The breeder's privilege

The 'breeder's privilege' or 'research exemption' noted above gave breeders the freedom not only to use protected plant varieties in their breeding programmes but also to commercialize the further varieties developed therefrom (often only 'cosmetically' different from the original) without any royalty payment to the owner of the initial variety. This freedom is modified in UPOV 1991. The first part of this freedom has

been retained in Article 15(1), which provides that the breeder's right does not extend to 'acts done for the purpose of breeding other varieties'. The second part has been curtailed as a result of the broadening of the scope of the right to 'essentially derived' varieties.

The freedom to research is safeguarded equally under both the patent law and plant variety rights (PVR) law, but the freedom to commercialize the resulting new varieties depends on whether or not they infringe the patent claims or are 'essentially derived varieties' under PVR law. The strengthened UPOV-type protection therefore goes part of the way towards the strong protection given by patents. Incidentally, neither system is a threat to the free use of existing germplasm, since these rights can in no sense monopolize known material as such.

The farmer's privilege

The ability to save and re-sow seed, as explained above, was a consequence of the restricted definition of the scope of the breeder's right. Recognizing that the current scale of use of farm-saved seed thus deprives the breeder of significant royalty income, the strengthened right under Article 14 of UPOV 1991 now makes all propagation subject to the authorization of the breeder. However, contracting states can 'reintroduce' this freedom under their national legislation 'within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder'. According to Article 14(3) of the European Community Plant Variety Rights regulation, the royalty rate on re-use of saved seed is to be 'sensibly lower' than that for bought-in seed.

Now that the 1991 UPOV no longer prohibits the availability of both types of legal right (patent and PVR), plant breeders who are themselves using the techniques of biotechnology alongside traditional breeding methods will wish to obtain both types of protection as appropriate.

Invention, Protection and Exploitation

The legal principles discussed above may be better appreciated in the light of a concrete practical example. This example is taken from European Patent Publication No. 272,144 (also US patent No. 5,306,863) but the claims presented below have been drafted by the author for the purposes of the present discussion.

The gene responsible for producing a trypsin inhibitor in the cowpea (*Vigna unguiculata*) has been transferred to other genera of plants. The cowpea is a legume, also called black-eyed bean, which is grown as a food crop in West Africa and in both North and South America. The trypsin inhibitor produced by resistant varieties of this plant prevents invading insects from digesting protein so that they die of starvation.

Transfer of the inhibitor gene to other plant genera requires the methods of plant biotechnology and cannot be achieved by traditional breeding methods. The technology is aimed at protecting cotton and cereals against bollworms of the genera *Heliothis* and *Anthonomus*, which affect these crops throughout the American and African continents. It is applicable also for protection of grain of wheat, maize, rice and sorghum against storage pests of the genera *Tribolium*, *Sitophilus* and *Chilo*, the latter being particularly serious in Africa, India, China and Japan.

Considering this invention first from the aspect of patenting transgenic cotton plants, the following types of claim are conceivable: (i) a transgenic cotton plant having a gene for a trypsin inhibitor (type 1); (ii) a transgenic cotton plant having a gene for a trypsin inhibitor derived from the cowpea (type 2); and (iii) a cotton plant of the variety Stoneville 825 containing a gene for a trypsin inhibitor derived from the cowpea (type 3).

How should these claims be treated in official examination by patent authorities? Before the most recently decided EPO case law to be described below, the EPO would allow claims of type 1 and 2 because the plants are not claimed at the varietal level of definition. Each of these claims will cover all manner of varieties of cotton in which the gene has been introduced but patentability should not be affected by this fact. The claims should be allowable or not depending on whether or not they express an invention, and the plants covered by the claims are not in any sense being patented as varieties but as articles embodying an inventive step.

Claim type 3 above is the only claim that mentions a variety and is thereby arguably open to objection. It is a strange result that the patent applicant is apparently barred from specifically claiming the application of his invention to a particular commercially important variety. Since the major crop plants are marketed as varieties, what use would a transgenic plant patent be if it did not cover such an application? This anomalous result is one unforeseen consequence of the desire to draw an absolute line between the two forms of legal protection. The transgenic process, whereby the foreign gene enters the genome of the starting variety, will not necessarily result in another variety in the older sense of the term, i.e. a distinct, uniform, stable variety. The process will produce the parental material from which further varieties will be bred. However, as a result of the new variety definition in UPOV 1991, the EPO has changed its attitude towards patent claims of the above type.

Commercial Exploitation

A typical pattern of the creation and exploitation of this type of technology could be as follows. A biotechnology research group in a scientific research institution or in an industrial research laboratory will have isolated the gene from the germplasm of the source country and will have patented the

gene construct and the method of gene transfer to the plants targeted for protection. The patent owner will be free to develop and exploit this technology commercially on his own behalf. But it may be better to license the technology to commercial plant breeders in industrially developed countries and to appropriate organizations in developing countries, e.g. state-run agricultural research institutes, together with the know-how to transfer the gene to chosen types of plant. The plant breeders or research institutes may obtain plant breeders' rights for any resulting varieties. The new varieties will be sold to farmers who will cultivate them and, as a result of their improved pest resistance, will be able to economize in the use of chemical pesticides. The public will benefit from the advantages to the environment resulting from this technology. It is difficult to see who will not gain from this achievement. Unless the transgenic plant enables the farmer to achieve a better yield or a saving on the use of insecticides, it will not be worth the higher price asked for it and it will not be purchased.

It remains to be seen whether the commercial exploitation of these forms of legal rights, either as alternatives or in combination, can be managed successfully without undue burden on farmers and other end-users. In the plant field, the negotiation of commercially reasonable royalty rates on farm-saved seed should not be unduly difficult and would avoid breeders having to ask high prices on the original sale of seed in order to recoup their investment in research and development in single payments. In the case of transgenic farm animals intended as breeding stock, it would be less easy to enforce rights through successive generations, and the animal breeders may well have to be innovative in devising commercially feasible methods of ensuring a return on their investment. In all cases, however, the continuing need to compete with traditional varieties and breeds ought to induce patent holders and PVR holders to follow reasonable policies. The 'Abuse of Monopoly' provisions that exist in both legal systems should also work towards the outcome of common sense.

Should Plant Varieties Remain Unpatentable?

The view has been held for some years in industrial and patent professional circles that a plant variety should be patentable provided that it meets the criteria of patent law. It has also been urged that both types of protection should be allowed (cumulative protection) provided the criteria under each system are fulfilled. These ideas began to gain a hearing in official patent circles, a noteworthy development, which was encouraging to those who have held their ground throughout this time (Straus, 1984). It should be noted that the suggestion applies to the patenting of the specific variety, as such, and would therefore require the abolition of provisions such as EPC Article 53(b).

Realistic commentators admit that most varieties of the kind typically presented for plant variety protection will not qualify for patent protection because of the difficulty of showing that they entail an inventive step. It would also be difficult to describe the method of breeding in a way that would be repeatable. Therefore, the PVR should remain as the preferred option for legal protection for innovations at the level of specific varieties.

The lack of examples of attempts to patent plant varieties of the typical kind for which PVR are granted has tended to give this debate an academic rather than practical character. However, the rejection by the Supreme Court of Canada of a patent application for a soybean variety produced by methods of cross-breeding and selection (Pioneer Hi-Bred, 1989) provides a model of the type of patent claim that would be presented for a variety obtained in this way. The application was rejected because it contained no description of the method by which the variety had been obtained. Although seeds of the variety had been deposited with a culture collection, in conformity with the widely established practice for microorganisms, the court did not accept the deposit as a substitute for a written description of the method of production. The Canadian court is in this respect out of line with the courts of the USA, Europe and Japan. The claim read:

> A variety of soybean plant characterised by having the following characteristics:
> Seeds:
> shape oblong
> surface sometimes wrinkled
> seed coat color medium yellow
> seed coat luster shiny
> hilum color light gray
> weight 18–20 grams per 100 seeds
> cotyledon color yellow
> and also, exhibiting longitudinal discoloration of the seed coat stemming from the hilum, visible in the event that the plant has experienced considerable environmental stress.
> Leaves:
> color medium green
> shape ovate
> plant pubescence color medium gray
> plant height 27–35 inches
> plant type with intermediate canopy, i.e. intermediate between slender and bushy
> plant habit indeterminate.
> Pods:
> color brown
> set scattered
> flower color purple
> hypocotyl color purple
> lodging score 2–3, on a scale of 1–5

> maturity group 0
> said variety resembling the soybean variety Corsoy with respect to plant shape, seedling pigmentation and leaf characteristics and the variety Portage with respect to seed size, and the variety Altona with respect to seed shape, and the variety Hardome with respect to color of hilum and is further characterized by being resistant to the fungus *Phytophthora megasperma* var. *sojae* (races 1 and 2).

This claim is based essentially on a listing of phenotypical properties. It might be difficult in many such cases to identify an inventive concept in any one such property or in a combination of such properties. This concrete example could help to clarify the issues in discussions between patent and UPOV circles that have hitherto often been at cross-purposes for want of a common understanding on terminology.

The Later Case EPC Law on Article 53(b)

In the case of Plant Genetic Systems (Plant Genetic Systems, 1995a, b) the EPO Technical Appeal Board upturned the hitherto prevailing interpretation of EPC Article 53(b).

Plant Genetic Systems' European patent 242,236 was directed to transgenic plants containing in their cells a gene that conferred resistance to the herbicide Basta. The most important claim (claim 21) was for a 'Plant, non-biologically transformed, which possesses, stably integrated into the genome of its cells, a foreign DNA nucleotide sequence encoding a protein having non-variety-specific enzymatic activity capable of neutralizing or inactivating a glutamine synthetase inhibitor under the control of a promoter recognized by the polymerase of said cells'.

The patent also had claims to the methodology for transforming the plant, and claims to the vectors, plant cells and seed. It is important to note that the claims were not limited to particular plant species but referred to 'plants' in general. Until this patent was challenged, the EPO had been willing to allow patents for plants defined in this generalized way, i.e. in non-variety-specific terms. The patent was opposed by Greenpeace, who based their arguments on both limbs of Article 53 of the EPC, set out below:

> European patents shall not be granted in respect of:
> a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
> b) plant or animal varieties or essentially biological processes for the production of plants or animals: this provision does not apply to microbiological processes or the products thereof.

The main attack on the patent was based on the morality and 'ordre public' provisions of Article 53(a), the argument being that it was immoral to 'own' plants, which were the common heritage of humankind. Greenpeace supported this by producing results of surveys/opinion polls taken in Sweden (only farmers were consulted) and Switzerland.

The Technical Appeal Board considered the morality objection in depth and rejected it. The Board set out principles that they considered relevant to the assessment of such objections, and their decision will be of greater use in cases where this objection is more appropriate than in one relating to plant biotechnology inventions. The Board considered the survey data as unrepresentative of attitudes in member states. Indeed, the Board evidently considered the morality objection misconceived in a case of this kind. As regards 'ordre public', the Board would have considered this if there had been any evidence that exploitation of the patent would 'seriously prejudice the environment'. No such evidence was produced by Greenpeace.

However, Greenpeace had also taken the Article 53(b) objection, arguing that the claims to plants and seeds would cover varieties formed from them and that essentially biological processes were involved. It was argued that the claims, 'although cleverly drafted in general terms, were in reality meant to cover plant varieties', which would be contrary to Article 53(b). Furthermore, 'when a claim covered something which was unpatentable, the whole claim was bad'.

In reaching its decision, the Appeal Board was clearly influenced by the fact that in the specific patent examples of producing the transgenic plant, the process began with named varieties. The Board noted that claim 21 was not drafted in terms of a variety 'because there is no reference to a single botanical taxon of the lowest-known rank', but it held that the claim to transgenic plants 'includes within its scope known plant varieties which have been genetically modified so as to be herbicide-resistant … ' and was therefore not allowable under Article 53(b). The Board also said that the claim 'embraces and encompasses' plant varieties, and it was therefore an attempt to evade the prohibition.

The Board also pointed to the new definition of a variety as given in the revised UPOV 1991 and held that the genetically modified plants were themselves new varieties according to the new definition. The Board held furthermore that the claim could not be allowed under the exception provided by the second half of Article 53(b) (the microbiological process exception) since the process of producing and propagating the transgenic plants, although it involved a microbiological step, was not a microbiological process when considered as a whole.

The Board allowed the claims to the transformation process and claims to plant cells but also rejected claims to plant cells when 'contained in a plant'.

Plant Genetic Systems appealed to the Enlarged Board of Appeal, which can review decisions of the Technical Boards in certain circumstances, including those where Technical Board decisions are inconsistent with one another. The Enlarged Board did not endorse the first part of the Technical Board's analysis (that the claim 'embraced' varieties). On their second point (that the transgenic plants were varieties), the Enlarged Board expressed no opinion, holding that it could not intervene because this was a new point, which involved no inconsistency with previous decisions.

The effect of this decision was that, although the process technology could still be patented, the specific refusal of product claims for transgenic plants was a setback for the plant biotechnology industry.

In the next case to be heard (Transgenic Plant/Novartis II, 2000), the Technical Board of Appeal referred the principles it had followed in the Plant Genetic Systems case to the Enlarged Board of Appeal. The product claim in the patent application was directed to transgenic plants having specific foreign genes that conferred resistance to pathogens. The decision of the Enlarged Board was made as a matter of law, and its effect goes beyond the specifics of the invention claimed in the patent application under review.

Making reference to the legislative history of Article 53(b), the Enlarged Board found itself unable to endorse the reasoning of the Technical Board in the previous case and it reached the following conclusions:

1. A claim of the type considered here does not identify plant varieties and, though it covers varieties, it is not a claim to a variety or varieties. A claim in which specific varieties are not individually claimed is not excluded from patentability under Article 53(b) even though it may embrace varieties.
2. Inventions ineligible for protection under plant breeders' rights are patentable under the EPC provided they fulfil patentability requirements.

However,

3. Plant varieties containing genes introduced by gene technology are excluded from patentability.

Conclusion (3) means that if the claim is directed to a specific variety it is excluded, even though it has been produced by gene technology rather than by traditional plant breeding.

Thus it would seem that this decision restores the interpretation of Article 53(b) as decided in the Ciba–Geigy case.

The Plant Genetic Systems case was decided before EU Directive 98/44 was finally issued, whereas the Novartis case was decided after this. Even though this Directive was not legally binding on the EPO Boards of Appeal, the Novartis decision was consistent with what the Directive provides as regards the patenting of plants. This topic is therefore addressed in the next section.

The EU Directive 98/44

The European Commission's proposal in October 1988, for a Directive to EC member states concerning the legal protection of biotechnological inventions accepted the early patent case law outlined above as its starting point. In order to ensure that patent protection was available for inventions in plant biotechnology, Article 3 of the Commission's original text of the Directive provided that 'biological classifications other than plant or animal varieties … shall be considered patentable subject matter'. After some years of discussion with official representatives of member states, and much effort to persuade the European Parliament to agree to the proposal, a final text of the Directive has at last been agreed.

Article 4(2) of Directive 98/44 provides that 'Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety'.

Although this Article does not make specific reference to the patenting of the plant *per se* (either a transgenic plant or other new type of plant), it may be taken to conform to the ruling of the Enlarged Board of Appeal of the EPO. Therefore, national patent laws in European countries will be in line with the EPC in this respect.

Thus, from both the EU Directive and the Novartis ruling, the following conclusions can be drawn:

1. A claim to transgenic plants *per se* will be allowable in principle provided the claim is not to be construed as directed (limited) to a specific variety or varieties, but
2. The fact that gene technology has been used to transform a plant will, however, not remove the claim from objection under EPC Article 53(b) and its national counterparts if the claim is directed to a specific variety that could be protected under UPOV.

Patenting Plant Genetic Material

In comparison with the problems of conflict between the legal systems for protecting plants, the patenting of plant genes in Europe is relatively straightforward and comparable to US patent practice. Genes are a special example of the broad class of naturally occurring materials that in appropriate circumstances can be patented. Where it is necessary to isolate and characterize a natural product and to devise a process for producing it, or using it, in quantity before it can be utilized by man for any practical purpose, the patent law offers scope for protection. Mere pre-existence of the substance, in admixture with vast quantities of other materials, is insufficient to contradict this view. This is the declared position of the WIPO (1988), of the EPO (1995) and of the EU Directive 98/44 (Ell, 1998).

Conclusion

The use of biotechnology to modify the genetic constitution of plants is capable of producing inventions that ought to be accommodated within the framework of the patent law without serious difficulty. Patent practice is proceeding on this basis in countries with a generous patent law, and patents for plants are being granted in appropriate instances. Nothing should be done to halt this trend. It is unrealistic to try to preempt the role of patents by seeking a dominant position for a new and improved UPOV system. No matter what improvements are made to plant variety laws, the protection is unlikely ever to reach the level offered by patents because it inherently lacks generic character, being always pitched at the level of specific varieties.

Nevertheless, it would be equally undesirable for the patent system to interfere with the law of PVR working within its own proper sphere of operation. For certain types of plants the securing of these rights is closely bound up with obtaining national listing of the variety before its commercialization. This connection reinforces the necessity for a flourishing PVR system for which there is no easy substitute or alternative. However, so long as patent law excludes the granting of patents for plant varieties, it is vital that the limits of this exclusion be clearly apparent in order to avoid confusion in the protection of those plant-related inventions that fulfil the criteria of patentability. With the benefit of the ruling in the Novartis case and EU Directive 98/44, it seems that this has now been achieved.

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18

Indonesia

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Introduction

This chapter covers intellectual property rights (IPR) in Indonesia, especially those related to biotechnology and agriculture. The chapter also discusses technology transfer opportunities.

National Perspective: Current Status of Intellectual Property Laws

In Indonesia, intellectual property law is administered by the Directorate General for Intellectual Property under the Department of Justice and Human Rights.

The first intellectual property law in Indonesia was a Copyright Law established in 1982, followed by the Patent Law in 1989 and the Trade Mark Law in 1992.

On 2 November 1994, Indonesia signed the Agreement on Trade-related Aspects of Intellectual Property (TRIPS) and ratified it with Law No. 7, 1994, and on 1 January 1995 Indonesia became a member of the World Trade Organization (WTO). Since then, in order to comply with the minimum standard of protection and other standards of TRIPS, Indonesia has further developed its intellectual property law.

The most recent conditions of the law are as follows:

1. Patent Law: Law No. 6, 1989, amended by Law No. 13, 1997, and amended further by Law No. 14, 2001.

 Intellectual Property Rights in Agricultural Biotechnology. Second Edition (eds F.H. Erbisch and K.M. Maredia)

2. Trade Mark Law: Law No. 19, 1992, amended by Law No. 14, 1997, and amended further by Law No. 15, 2001.
3. Copyright Law: Law No. 6, 1982, amended by Law No. 7, 1987, amended by Law No. 12, 1997.
4. Industrial Design: Law No. 31, 2000.
5. Design of Integrated Circuit: Law No. 32, 2000.
6. Trade Secret: Law No. 30, 2000.
7. Plant Variety Protection Law: Law No. 29, 2000, administered by the Department of Agriculture in the Ministry of Agriculture.

Indonesia is a member of several international conventions: (i) the Paris Convention for the protection of industrial property; (ii) the Patent Cooperation Treaty; (iii) the World Intellectual Property Organization (WIPO) Copyright Treaty; and (iv) the Bern Convention for the protection of Art and Literary Works.

The Patent Law and Plant Variety Protection Law Related to Biotechnology and Agriculture

Patent Law

The Patent Law in Indonesia started with Law No. 6, 1989, which was improved further by Law No. 13, 1997 and at present by Law No. 14, 2001.

Previously, in Law No. 6, 1989 in Article 7(c), it was noted that patents could not be granted for new varieties of plants and/or animals, or on any process used for the multiplication of plants and/or animals. Article 7 was deleted in Law No. 13, 1997, implicating that there are no restrictions for patenting plants and/or animals.

Furthermore, with the development of Law No. 14, 2001, Article 7 was reinstated. Article 7(d) states that patents cannot be granted on inventions regarding living organisms except for microbes; however, non-biological or microbiological processes for plant and/or animal production can be patented. In the clarification of Article 7 in Law No. 14, 2001 it states that the process for genetic engineering can be patented (www.dgip.go.id/indonesia/uu_pp/UU_P14.pdf).

The problem with the Indonesian Patent Law is the fact that, although the biotechnology process can be patented, the product, if a living organism, cannot be patented or covered by a patent claim, because the product (if it is not in the form of microbes) will be categorized as a living organism. For biotechnology inventions resulting in a modified organism, the process of 'making' the organism can be patented, but the modified organism, which cannot be protected, could be reproduced by other means. Therefore protecting the process without covering the product will not give sufficient protection.

Furthermore, it is not clear whether a gene can be patented or not. Article 7(d) mentioned that a patent cannot be granted for an invention regarding living organisms; however, no mention was made about patenting part of a living organism such as a gene. It is evident that a 'petty patent' or 'utility model' according to Indonesian patent law cannot be used to protect a gene, because a petty patent covers a new product or device having practical use as a result of its form, configuration, construction and/or components.

Another important article in the Indonesian Patent Law is Article 17(1) which contains provisions that the patent assignee has to produce and use the patent right in Indonesia. However, an exception can be made if the production or the use of this process can only be done or is only suitable to be produced regionally (Article 17(2)).

Plant Variety Protection Law

Breeding new varieties of plants requires a substantial investment in terms of skill, labour, material resources, money and time. The opportunity to obtain certain exclusive rights with respect to a new variety provides the successful plant breeder with a better chance of recovering costs and accumulating the funds necessary for further investment.

In the absence of plant breeders' rights, those aims are more difficult to achieve, since there is nothing to prevent others from multiplying the breeder's seed or other propagating material and selling the variety on a commercial scale, without recognizing in any way the work of the breeder.

However, protection by patent will mean that farmers cannot use their harvested materials as seed for the following season. Some exceptions would be needed so that the protected varieties can still be used for other, non-commercial purposes, such as for breeding new varieties and for experimental research. In order to comply with TRIPS and to develop agriculture by attracting private sector investment, Indonesia chose to forbid patenting of plants and protect new plant varieties through the Law of Plant Variety Protection.

The Indonesian Law of Plant Variety Protection is based on the International Union for the Protection of New Varieties of Plants (UPOV) Act 1991 with several modifications.

To be protected, a new plant variety must fulfil several requirements. It must be:

1. *New*. The variety shall be deemed to be new if, at the date of filing the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety.

2. *Distinct*. The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of filing the application. In particular, the filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be.
3. *Uniform*. The variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics.
4. *Stable*. The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.

Several important articles from Section Five of the Rights and Obligations of Plant Variety Protection Holders of the Indonesian Plant Variety Protection Act are as follows.

Article 6

1. Plant Variety Protection Holders have the right to use and give an authorization to people or other legal entities to use the variety as a seed and harvested materials used for propagation.
2. The rights mentioned above also cover:
(a) varieties that are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety;
(b) varieties that are not clearly distinguishable from the protected variety; and
(c) varieties whose production requires the repeated use of the protected variety.
3. The rights to use a variety as mentioned in paragraph (1) cover the activities:
(a) production or reproduction (multiplication);
(b) conditioning for the purpose of propagation;
(c) advertising;
(d) offering for sale;
(e) selling or other marketing;
(f) exporting;
(g) importing;
(h) stocking for any of the purposes mentioned in (a) to (g), above.
4. The use of harvested materials for propagation as mentioned in paragraph (1) from protected varieties shall require authorization from Plant Variety Protection Holders.

5. The use of essentially derived varieties from the protected varieties as mentioned in paragraph (2) shall require the authorization from Plant Variety Protection Holders with the definition of essentially derived varieties as follows:

(a) It is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(b) It is clearly distinguishable from the initial variety and except for the differences that result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(c) Essentially derived varieties may be obtained, for example, by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

6. The source varieties used to produce essentially derived varieties have to be named and registered by the Government.

7. The regulation about giving a name, registering and utilizing a variety as a source variety for essentially derived varieties (for instance, a variety used as a parent variety for hybrids), as mentioned in paragraph (5) and paragraph (6), and the institutions for the implementation of registration will be defined further in the implementing order.

Article 10. Exceptions to the Breeder's Right

1. The breeder's right shall not extend to:

(a) the use of a part of harvested materials from the protected variety as long as not for commercial purposes;

(b) the use of the protected variety for research purposes, plant breeding and to form a new variety;

(c) the use of the protected variety by the Government for food and medicinal purposes with consideration to the economic rights of the Plant Variety Protection (PVP) holders.

The consequences of Article 10 are that farmers have the right to use their harvested materials for their source of seed in the following season and that the plant breeder has the right to use protected varieties for breeding new varieties. The protection given to the plant breeder covers registered varieties and its essentially derived materials. The protection over the essentially derived varieties serves dual purposes, i.e. a breeder cannot register a new variety simply by adding a gene through genetic engineering, moreover another party cannot simply take a variety, mak-

ing a small improvement and register it as a new variety. However, since genetic transformation is expensive, there is the concern that a gene could be inserted into a new variety by breeding.

Other important articles are Article 7, containing provisions stating that local varieties are protected by the State; Article 9, concerning obligations of the PVP holder to produce the variety in Indonesia; and Article 44 about compulsory licensing after 36 months.

The Impact of the Patent Law and the Plant Variety Protection Law on the Development of Biotechnology in Indonesia

The impact of both laws on the development of biotechnology can be viewed from two angles – Indonesia as a technology consumer and as a technology producer.

Indonesia as a technology consumer

From the technology consumers' point of view, the existence of patent law will protect biotechnology products aside from transgenic plants. For a transgenic invention, protection given in Indonesian patent law is only for the process and does not cover the product, and thus transgenic plants may be reproduced using other means.

The Plant Variety Protection Law is new and not yet implemented, and the exception in Article 10 may make the private sector wonder whether there will be enough coverage to protect their economic interests. As a result of this, it seems that in the near future, the private sector will only invest in a transgenic plant if there is an 'additional protection', such as integrating a gene into a hybrid maize, or, in the case of Bt cotton (transgenic cotton using genes from *Bacillus thuringiensis*), because of the direct close cooperation between farmers and the private sector owning the gene and the harvest products that are bought by a subsidiary of the technology provider. For rice and soybean, commercial development will be much slower because, at present, there does not appear to be a means of providing adequate protection.

Indonesia as a technology producer

Indonesia has the potential to produce biotechnology products. The existence of the Patent Law is likely to be a positive factor for the development of biotechnology applications. However, for transgenic plants there will be a different story. Although several institutions such as the Agency for

Agriculture Research and Development (AARD), the Indonesian Institute of Sciences and the Bogor Agriculture University have the human resources and equipment needed to produce transgenic plants, there are constraints for commercialization, since most of the genes, plasmids and technologies used usually come from developed countries and are owned by the private sector. The private sector is currently reluctant to provide biotechnology tools beyond research-only use. Several constructs currently being utilized in biotechnological experiments are from several foreign research institutes under material transfer agreements allowing for research use only. Many of the patented biotechnology tools prevent commercialization unless there is adequate protection in Indonesia.

Several transgenic plants are already in the later stages of development, such as Bt rice in the Indonesian Institute of Science and several others at the Research Institute for Agricultural Biotechnology (Table 18.1). However, the commercialization of these plants will be subject to some intellectual property (IP) problems, because the material transfer agreements for the constructs restrict the use of these constructs for research purposes only.

Indonesian researchers have several choices to alleviate the IP problems:

1. Ignore IPR completely. Patent laws are territorial in nature. IP that is patented abroad will have no protection in Indonesia unless also patented in Indonesia. However, there will be implications, because ignoring IPR means losing credibility and it may be difficult for the Research Institute in Indonesia to continue or initiate research relationships.
2. Use public domain technology from various international institutes such as the International Rice Research Institute, the International Maize and Wheat Improvement Center, the Center for the Application of Molecular Biology to International Agriculture: Australia, etc.

Table 18.1. Transgenic plants developed in Indonesia.

Plant	Character or trait
Maize	Stem borer resistant[a]
Groundnut	Peanut stripe virus resistant[a]
Cocoa	Pod borer resistant
Soybean	Pod borer resistant
Rice	Stem borer and brown plant hopper resistant
Papaya	Papaya ring spot virus resistant
Sugarcane	Stem borer resistant
Tobacco	Tobacco mosaic virus resistant
Sweet potato	Resistant to *Cylas* sp.
Potato	Potato tuber moth resistant[a]
Sweet potato	Sweet potato feathery mottle virus resistant[a]

[a]Transgenic plants developed through collaborative research.

3. Work together with a gene proprietor to develop a cooperative research agreement and share the economic benefits from the results.
4. Use limited licensing. Several constructs may be available from the proprietor as long as the use will not in any way interfere with their economic interests. A cooperation programme between Association of South East Asian Nations countries facilitated by the International Service for Acquisition of Agrobiotechnology Applications (ISAAA) obtained a gene that delays ripening that could be inserted into papaya. ISAAA was able to procure this genetic material because the gene proprietor did not have an interest in papaya.

Technology transfer in Indonesia

Before 1994, most of the technologies developed at public sector research centres in Indonesia were public domain technology. There was a little effort to license the technology and most of the researchers were satisfied with research publications. However, after 1994, Indonesia began to realize the importance of technology transfer to private sectors, in order to attract private sector investment in research and promote domestic technology. Promotion of IPR concepts and technology transfer begin in early 1998; several government offices such as the Ministry for Research and Technology, the Directorate General for Intellectual Property and the Directorate General for Higher Education were involved in the process.

The Indonesian Ministry for Research and Technology is involved in providing several forms of annual competitive grants, namely, RUK, OLEH PATEN, OLEH DESAIN, ASTEKNO, SENTRA HKI and TEMU BISNIS, which are described below.

1. RUK. Riset Unggulan Kemitraan (Cooperative Outstanding Research) is a competitive grant given to encourage research cooperation with the private sector. In this programme, a grant is given to a research establishment engaged in a cooperative research programme with the private sector in developing a new technology. A portion of the research expenses are from the private sector, and the research results are used by the private sector through a licensing arrangement or licence agreement.
2. OLEH PATEN. OLEH PATEN is a competitive grant given to an institution whose outstanding research results are to be patented. The cost of the patent application is paid by the State through this grant programme.
3. OLEH DESAIN. OLEH DESAIN is a competitive grant given to an institution whose outstanding product design is to be registered. The cost of the design registration is paid by the State.
4. ASTEKNO (Insurance for technology). To encourage technology development, the Ministry for Research and Technology (MRT) encourages the private sector to insure research that may develop into commer-

cial products. Several insurance brokers are willing to insure technology development in case of *force majeure*, etc. Premiums for the insurance are paid by the State.
5. SENTRA HKI (IPR Centres). In order to promote technology transfer, MRT is giving seed money based on competitive proposals to build IPR centres or technology transfer offices in research institutes or universities.
6. TEMU BISNIS. In order to help the IPR centres promote their products, competitive grants are given to IPR centres at research institutes or universities.

The Directorate General for Intellectual Property and the Directorate General for Higher Education have been involved in the process of promoting IP management by creating several training programmes, workshops and conferences. One of the programmes is the Indonesia Australia Specialized Training Program (IASTP), which has been funded by the Australian Agency for International Development since 1998. This programme has already trained 809 Indonesians in IPR; additionally 117 in Australia and 631 in Indonesia have also been trained in IPR management and other matters.

As a result of these programmes, 91 IPR centres have been built throughout Indonesia and they are now gathering to form an association called Asosiasi Sentra HaKI or the Association of IPR Centres. This association aims to develop cooperation amongst the IPR centres with the hope of mimicking the success of the Association of University Technology Managers in the USA.

Technology transfer in agriculture

One example of technology transfer in agriculture is what happened within AARD in Indonesia. Since the early 1990s, AARD has had a close cooperative research relationship with Michigan State University (MSU); especially after the initiation of the Agriculture Biotechnology Support Project (ABSP). The research cooperation activities included training at MSU in biotechnology research techniques as well as IPR management.

Using the IPR management training from MSU, the Intellectual Property and Technology Transfer Office of the AARD was established in July 1999. This office is called *Kekayaan Intelektual dan Alih Teknologi* (KIAT) in Indonesian. The office is part of the Indonesian Agricultural Research Foundation, a private non-profit organization established by the national government to facilitate technology transfer, licensing and commercialization of agricultural technologies developed through conventional and biotechnology methods. The general director of AARD serves as a member of the board of trustees for the Foundation. Being a private and non-profit organization, the Foundation is able to interact

freely in dealing and doing business with the private sector. Funds received by the Foundation, including those received by KIAT, are used to finance the operating costs of KIAT, pay royalty shares to researchers, provide research support and cover IP protection fees.

KIAT serves as the main focal point for technology transfer within AARD and is responsible for serving 31 agricultural research and socio-economic assessment institutes of AARD located across Indonesia. Through KIAT, several licence agreements to commercialize a wide range of agricultural technologies, such as bio-fertilizer, bio-bactericide and hybrid maize, have already been negotiated. KIAT has licensed a *Rhizobium*-based bio-fertilizer for soybeans to a private company for production and sale throughout Indonesia. The company pays royalties and provides quality control services. A series of hybrid maize varieties has been licensed to a leading seed company owned by the government of Indonesia. This company buys parent stock of maize and develops the market with the assistance of AARD researchers. Most recently new varieties of chrysanthemum, rose, potato and hybrid rice were also licensed.

An animal vaccine technology development programme is also being developed. Nearly all of the animal vaccines sold in Indonesia are imported from abroad. The Research Institute for Veterinary Science in AARD has already developed several animal vaccines that have proved to be effective for Newcastle Disease in chickens, as well as brucellosis in ruminants. KIAT will facilitate licensing of these vaccines to the private sector for marketing in Indonesia.

KIAT will play a role in educating AARD researchers and administrators on various aspects of IP and technology transfer. The office will also facilitate the establishment of spin-off companies based on technologies generated from AARD research.

KIAT is playing a role in technology transfer regionally, interacting with several different institutes such as MARDI in Malaysia, the National Center for Genetic Engineering and Biotechnology in Thailand, The Institute of Biotechnology in Vietnam and the Institute of Biotechnology in the Philippines. KIAT initiated the Intellectual Property for South-East Asian Network on Intellectual Property and Technology Transfer Management programme. One of the initial activities of the network is an IP audit, which provides hands-on training and facilitates technology transfer in Thailand, Malaysia, Vietnam, the Philippines and Indonesia. In September 2002, the network, together with BIOTEC in Thailand, hosted BIOLAW 2002, a workshop for law and biotechnology.

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Exercising Intellectual Property Rights Management In Brazil: Research, Technology Transfer and Agribusiness After TRIPS

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Introduction

The Trade-related Aspects of Intellectual Property Rights (TRIPS)[1] allows considerable flexibility in how countries may design their intellectual property (IP) system. Brazil adopted its minimum standards in 1996 when Congress reviewed the existing Industrial Property Law. Some of the changes helped to clarify the status of protection in the agricultural biotechnology area. However, the opportunity to patent microorganisms was only opened for 'genetically modified' microorganisms (Law No. 9.279[2]/1996). Brazil has also adopted a Plant Variety (or Cultivar) Protection Law (No. 9.456[3]) in 1997, following the International Union for the Protection of New Varieties of Plants (UPOV) 78 model that has been implemented with success since 1998 covering more than 30 species. To complement the IP framework as it relates to agriculture and agribusiness, Brazil is implementing a recently approved Provisional Law on Access to

[1] Approved during the Marrakesh Round, in 1994, TRIPS was incorporated as Annex 1C of the General Agreement on Tariffs and Trade (GATT), approved during the Uruguay Round, in 1995.
[2] Law No. 9.279 is implemented by the Industrial Property National Institute (INPI), linked to the Ministry of Industry and Commerce (MDIC) (www.inpi.gov.br).
[3] Law No. 9.456 is implemented by the Cultivar Protection National Service (SNPC), linked to the Ministry of Agriculture, Livestock and Food Supply (MAPA) (www.agriculture.gov.br/snpc).

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Genetic Components and Resources (No. 2.186–16[4]/2001) and has signed (June, 2002) and will probably ratify the Food and Agriculture Organization (FAO) Treaty on Genetic Resources for Food and Agriculture.

Based on this new legal environment, most of the universities, public research institutes and governmental or private funding agencies are actively investing in bringing together administrative structures responsible for the implementation of intellectual property rights (IPR)-related activities, including policy making and technology transfer. Some examples are the Oswaldo Cruz Foundation (Fiocruz, www.fiocruz.br), linked to the Ministry of Health, with a unit called GESTEC; the São Paulo Research Foundation with a unit called NUPLITEC; the University of Brasilia with a unit called NUPITEC; the Federal University of São Paulo where activities are developed by a Institutional Marketing Committee; and the Brazilian Agriculture Research Corporation (Embrapa) with a unit called SPRI, among others.

To increase support for the creation of a better structure, the Ministry of Science and Technology launched a special programme in 2002 giving incentive to the training of personnel and to link the IP offices in a dynamic network. These offices should provide expert advice to researchers who can now expect to have some economic return from their inventions, including new cultivars. As the potential audience grows, many national and international seminars on the subject are taking place, either organized by private law offices or by IP associations such as IBPI (National IP Institute, founded in 1983), ABPI (Brazilian IP Association, founded in 1963, www.abpi.org.br), ABAPI (Brazilian Association of Industrial Property Agents, founded in 1948), ASPI (IP Association of the State of São Paulo, founded in 1983), ABIPTI (Brazilian Association of Technological Research Institutions, founded in 1980, www.abipti.org.br) and many others.

Therefore, the use of IPR in the areas related to agriculture and agribusiness in Brazil seems to pose an exception to some of the major conclusions of the recent report on IPR-related aspects presented to the London Commission on Intellectual Property Rights by a group of experts (Barton, 2002). Brazilian institutions have made much progress in sharing the potential benefits from classical or biotechnological inventions and are learning to discuss, prepare and implement complex contracts with the private sector, be it national or transnational, as was predicted some years ago (Sampaio and da Cunha, 1999), allowing the development of new views on how to strategically plan research and associated business. A major effort is also being devoted to IPR management by public institutions in the health area, i.e. the Oswaldo Cruz Foundation, which started the process in the early 1990s with increasingly positive results (see Table 19.1).

[4] Provisional Law No. 2.186–16 is implemented by the National Management Council, linked to the Ministry of Environment (MMA) (www.mma.gov.br/cgen).

Table 19.1. Patent management at the Oswaldo Cruz Foundation (Fiocruz), Ministry of Health,1995–1999. (From Gestec, 2001.)

Indicator/year	1995	1996	1997	1998	1999
Patents filed in Brazil	1	1	4	5	5
Patents filed abroad	3	6	0	12	11
Patents received in Brazil	0	1	1	7	0
Patents received abroad	0	0	3	10	1

IPR Management at the Brazilian Agricultural Research Corporation (Embrapa) – a Learning Curve

Management of IPR is a key skill for any research institute (Trigo *et al*., 2002). Minimum requirements are a well-discussed policy and trained personnel. In order to implement its IP policy, which was published and incorporated as internal rules in 1996, Embrapa created a centralized 'Office' called the *Intellectual Property Secretariat* (Sampaio and da Cunha, 1999). Its overall mission is to coordinate Embrapa's proprietary technology acquisitions and also organize the process of licensing out Embrapa's major proprietary assets – new cultivars. In addition, the office constantly reviews Embrapa's IP policy, making necessary adjustments in accordance with the changing global developments. As the diverse nature of Embrapa's research programme makes it very difficult to train personnel with the required expertise needed to respond to the complex issues involved in IP protection and business negotiations, the initial decentralized mode of action proposed in 1998 is slowly moving to a very centralized operation (Sampaio, 2002) where opportunities and risks can be visualized and compared by a group of experts (lawyers and scientists in biological areas).

Based on the concept that it is easier to reach a goal when both parties have an interest in a business deal, Embrapa's IP office has been developing the practical work necessary for the protection of products and processes generated by Embrapa's research programmes (see Tables 19.2 and 19.3), has been involved in developing model contracts with the private sector, such as MTAs (material transfer agreements) and research agreements, and FTO (freedom to operate – the negotiation of necessary licenses for the use of third party(ies) proprietary assets; see comments below and Table 19.3). However, it has also evolved to become a policy-making unit, continuously demanding that Embrapa faces its challenges in a more professional and competitive style. Many 'star' players have had to be aligned to allow for current results – most essential was total support from the company's higher management, a close interaction with research leaders, support from the different Government financing agencies, support in Congress for changes needed in the legislation and,

Table 19.2. Number of cultivars of some commodities under protection in Brazil since the approval of the Plant Variety Protection Law (1998–2002).

Crop	All breeders/owners of variety[a]	Embrapa[b]
Sugarcane	35	–
Potato	21	2
Rice	24	15
Maize	20	18
Beans	9	2
Cotton	18	14
Soybean	180	74
Wheat	32	13
Sorghum	5	5

[a]Public and private institutes.
[b]Public institute.

Table 19.3. Number of patents filed before and after the implementation of IPR regulations and incentives at Embrapa in 1996.

Type of protection	Before 1996	1997–2002
Utility patents	20	105 (Brazil) + 35 (PCT)
Trademarks	23	137
Software	5	21

most of all, a stable political environment, which has been possible in Brazil for the past 8 years and which is essential for the development of research and a business environment.

Having these parameters in place has prompted the IP office to work very hard to implement several complementary measures to help Embrapa to improve its already valuable portfolio. Such policy measures, which directly reflect on the research programme, relate to the enrichment of germplasm banks, the organization of molecular characterization/sequencing data banks, the storage of characterized cDNA libraries and the development of rules for strategic germplasm exchange (both in accordance with the new national Access legislation and in preparation for the implementation of the new FAO Treaty on Plant Genetic Resources). On a similar note, Embrapa's IP office is to produce a set of regulations for germplasm exchange with the CGIAR Research Centres (Consultative Group on International Agricultural Research, www.cgiar.org) and is at present studying the international situation regarding crops that are under CGIAR responsibility and will eventually compose the Multilateral System of Facilitated Access and Benefit-sharing

– the centrepiece of the FAO Treaty. Until the rules set forth by the specially designed MTA become available,[5] it will be necessary to set provisional rules, taking into consideration the fact that breeders and hence breeding programmes will not be able to easily differentiate whether a gene has been moved before or after the Treaty of the Convention on Biological Diversity (CBD) has entered into force. In its latest development (9–11 October 2002), the First Meeting of the Commission on Genetic Resources for Food and Agriculture acting as Interim Committee for the International Treaty on Plant Genetic Resources for Food and Agriculture elected an Expert Group to build on the terms of the 'Standard Material Transfer Agreement' called for by the Treaty. The Group will meet in 2003 to answer some very intricate questions such as: (i) When would a product be considered to be available without restriction to others for further research and breeding?; (ii) What terms should be included in the MTA so that recipients are bound to them upon acceptance of the material from the Multilateral System?; (iii) What should be the level, form and manner of payment of royalties in line with commercial practice?; and so on (CGRFA/MIC – 1/02, draft report part 2). At this stage, it is a blessing that the Brazilian Access Law does provide for an exception to materials included in the Multilateral System of Facilitated Access and Benefit-sharing. Embrapa introduced this clause in the text of the law to avoid a future conflict of both regulations over the same germplasm.

International fora

At the international level, the IP office staff navigates between Mercosur (Free Trading Area of the South Cone, including Argentina, Paraguay, Uruguay and Brazil) and FTAA (Free Trading Area of the Americas, also known as ALCA) preparatory meetings as a member of an interministerial IP discussion group (GIPI), which is responsible for the preparation of positions defended by the Brazilian Delegation at these meetings. The same is true for the World Intellectual Property Organization (WIPO) meetings on Genetic Resources, Benefit Sharing and Traditional Knowledge and the on-going TRIPS review meetings, which are followed by External Affairs officers and by staff of the Industrial Property National Institute (IPNI). The IPR aspects of the Convention of Biological Diversity, the FAO Treaty, as mentioned above, and other relevant fora are all closely monitored by Embrapa's IP Office as they have a direct impact on IP management by the company.

[5] The Treaty will enter into force on the 90th day after the deposit of the 40th instrument of ratification, acceptance, approval or accession, provided that at least 20 instruments of ratification, acceptance, approval or accession have been deposited by Members of FAO. To date, eight such instruments have been deposited while 60 countries have already signed the Treaty (www.fao.org/agriculture).

Implementing PVP through partnerships with the private sector: finishing varieties and multiplying seeds under special risk contract agreements

The opportunity for plant protection gave Embrapa and other breeding institutions in Brazil the necessary tools to negotiate a better partnership with the private sector based on mutual benefit. One of the models that was developed consists of a business contract that guarantees that the private financial investment during the later phases of the variety breeding is compensated by a 4–8 year period of priority in seed multiplication and selling with due retribution of royalties to Embrapa. To guarantee the fulfilment of its public mission, Embrapa does not grant the property of the variety to the third party. The new cultivar is always protected and registered in the sole name of Embrapa because this facilitates any new negotiation and also avoids the transference of publicly owned germplasm to private hands. Embrapa will file for co-ownership when the third party is another public institution. Many new foundations (organizations formed by seed producers and farmers) have been formed over the last 3–4 years in regional schemes ensuring the multiplication and distribution of every new cultivar that is ready for the market. A recent unpublished survey has shown that for most crops there has been a slow and steady substitution of public varieties for protected varieties since the farmer is constantly looking for better productivity and seed quality. For soybean, the substitution has already reached 100%. Up to 2001, Embrapa had almost 2000 licensing contracts negotiated with more than 30 private and public partners. From these contracts there has been an increasing return of revenues, which are immediately reinvested in research. However, there is a word of caution – contract management is not an easy task and needs to receive due attention if the institution is really to benefit from all these arrangements.

Obtaining the freedom to operate

Genes straddle the boundary between patentable and unpatentable substances because DNA sequences are not simply chemical molecules but also information (Eisemberg, 2000). While the debate on gene patenting goes on (Andrews, 2002), modified genes and genetic elements such as promoters are being patented by the US Patent Office and by other similar offices around the world. To the research users, problems arise when the owner decides to protect his/her invention to avoid early interference by competitors. To help in this context, the information recently made available by CAMBIA (www.cambia.org) with the support of the Rockefeller Foundation is the first complete FTO study that can help developing countries to map their opportunities and restrictions, in this particular case, using the *Agrobacterium tumefaciens*-based transformation

method. This is the type of study that research institutes all over the world are eager to have available. The effort should expand to include other basic enabling technologies.

As well as working to license out the institution's proprietary assets, an IP office must implement constant audits of research projects and, when possible, this should be done in an *ex ante* fashion. This is to avoid later deceptive situations, as not every construct or element or component used by the unaware researcher may be available for licensing. As an audit developed by Embrapa's IP office during 2001/2002 shows (see Table 19.4.), as many as 15 biotech projects involving ten different crops were using the 35S promoter, the patent for which has been granted, in Brazil, to Monsanto. As some of the products are nearing the final phases of biosafety assessment, which are very expensive, Embrapa decided to make an official enquiry to Monsanto about its position on the licensing of the technology, in the expectation that the company would differentiate its fees for 'social or more neglected' crops and the usual commodity crops. Unfortunately, an answer was not available in time to be included in this chapter. However, this example shows that negotiation of due IPR licences should take place as early as possible for any project that is intended to develop a product for commercial application. Furthermore, if the experimental use exemption provided for in the US Patent Law begins to be interpreted around the world, as in the recent decision of the US Court of Appeals for Federal Circuit in Maddey v. Duke University, No. 01–1567 (3 Oct. 2002), as applying only to uses of the patented article or process 'for amusement, to satisfy idle curiosity or for strictly philosophical inquiry', the result could be that the user will be disqualified from the exemption if the use has 'the slightest commercial implication'.

Policy making: activities for the intellectual property office that go beyond Embrapa

Some new challenges have recently been added to the office's policy making efforts, which have large interfaces with the application of IPR, and far from being a concern for Embrapa only, could deeply modify the opportunities for different players in the agribusiness. First, there has been discussion of a proposal by the Government for an Innovation Law, which will involve regulations regarding permission for public employees (researchers) to work inside private companies or open parallel small businesses (technological 'incubators') with Government incentive or with venture capital (as it is already happening in the genomics and bioinformatics areas (see below)). Secondly, there has been discussion in Congress of a new Seed Law, which has been extensively revised together with the private sector and congressmen to

Table 19.4. 35S promotor (Monsanto's patent PI 1101063-0 in Brazil) and other components being used in product development at Embrapa.

Component	Crop/application	Genes to be expressed
Promotor (e35S AMV leader sequence) Terminator CAMV35S	Common beans/ golden mosaic virus control	35S promoter has been used to drive the replicase gene of bean golden mosaic virus, isolate from Brazil
Promotor (e35S AMV leader sequence) Terminator CaMV35S	Rice/*M. grisea* (brusone) control	Amphibian isolated peptides
Promotor (e35S AMV leader sequence) Terminator CAMV35S Marker – *npt*II	Passion flower/ *Xanthomonas* control	Sarcotoxin gene isolated from *Sarcophaga peregrina*
Promotor (e35S AMV leader sequence) Terminator CAMV35S Marker – *npt*II	Banana/*Fusarium* control	Amphibian isolated peptides Gene to be isolated
Promotor (e35S AMV leader sequence) Terminator CAMV35S Marker – *npt*II	Papaya/lethal yellowing virus control; sticky decease (Meleira) virus; ring spot virus control; shelf life	Coat protein genes or other sequences isolated from the Brazilian virus genomes to explore post-transcriptional gene silencing for pathogen-derived resistance
Promotor (e35S AMV leader sequence) Terminator CAMV35S Terminator *nos*	Soybean, common beans/ co-transformation systems with herbicide markers	Marker gene EPSPS (to be licensed from Monsanto)
Promotor 35S Terminator CAMV35S	Cotton/boll weevil resistance	Bt-like genes Genes being characterized from Embrapa's Bt collection
Promotor (e35S AMV leader sequence) Terminator CAMV35S Marker – *npt*II	Maize/ co-transformation systems with herbicide markers; aluminium tolerance and phosphate utilization	Citrate synthase
Promotor 35S CaMV Terminator *nos* Marker – *npt*II	Potato/PVY resistance; PLRV resistance	Coat protein gene, isolate from Brazil pPLRV – potato leaf roll virus

include features that respond to the differential market created after the implementation of the Plant Variety Protection Law. Thirdly, there has been preparation of the text with the necessary modifications in the 1997 Plant Variety Protection Law to include all the 1991 UPOV Act characteristics.

At the same time, under the IP office coordination, a group of scientists has been involved in discussing and adapting DUS (distinctness, uniformity, stability) tests for new cultivars under Brazilian conditions, as required for their protection. Other groups, along with external collaborators, have been busy preparing descriptors for new species to be included in the list of protected materials, as Embrapa is supposed to give technical support to the official Cultivar Protection Office[6] (SNPC), linked to the Ministry of Agriculture, Livestock and Food Supply.

Last but not least, and with a large interface with IP, the office has been involved since 2001 with the implementation of a provisional law published by the Government on Access to Genetic Resources (or Genetic Patrimony), Related Traditional Knowledge, Benefit Sharing and Technology Transfer. The proposed Genetic Patrimony Management Council was nominated and began its deliberations in April 2002. The Council should provide the research community and other interested players with models for MTAs and contracts, which have to be negotiated before any collection or exchange of germplasm can take place. The law says that the Council should authorize each of the research institutions to develop these activities, and the IP office, in partnership with Embrapa's Genetic Resources and Biotechnology Unit, is gathering information from its National Germplasm Bank Network (with more than 160 *ex situ* germplasm banks spread around the country) to provide to the Council and hopefully obtain Embrapa's authorization to restart these activities and related research projects. The implementation of each MTA and/or Bioprospecting Contract will be a responsibility of the IP office in conjunction with Embrapa's Genetic Resources leading units. According to the provisional law, contracts will have to be submitted to the Council for final approval, a step that may complicate discussions of IP clauses and business negotiations. Timing will be important. However, this is the beginning and the IP office will play an important educational role in the coming years until enough experience and confidence is built and less restrictive steps can be taken.

Human Resources – Increasing Efforts in Biotechnology and Demand for More IPR Management Skills

Brazil is the largest producer of science in Latin America based on a total of approximately 200,000 people, including students, trainees and

[6] To date, 30 species can have their cultivars protected (list available at www.agricultura.gov.br/snpc) and another five have documents under preparation. Strong pressure for urgent approval of descriptors is coming from the ornamental business sector.

researchers in the private and the public sectors. There are 18 university degree programmes with special focus on biotechnology. Ten universities grant MSc level degrees while eight are already granting both MSc and PhD level degrees. Research and development (R&D) activities range from natural products and processes and animal breeding and cloning to plant biotechnology, biopharming, and human genomics and molecular biology. It is estimated that approximately 52,000 researchers are involved with R&D activities in several sectors and in areas of great importance to biotechnology.

A survey coordinated and conducted by CNPq (National Research Council, www.cnpq.br) in 2001 pointed out that there were 1718 research groups located in universities and public institutions directly or indirectly involved in studies related to biotechnology. These specific groups comprised 6738 researchers and more than 16,000 students and trainees, totalling 20,000 people. The lack of new opportunities to increase in-house personnel during the last few years has brought an almost total dependence of public research institutes on students, opening a tremendous opportunity for these young people to have a very early contact with real science. In some ways, this is a very positive change, but has the drawback that results may take longer and be more expensive to produce because of 'hands-on' training and the natural turnover.

Knowledge Expansion in Biotechnology – Genomics, Bioinformatics and IPR Rules

Largely anchored in public research institutions, biotechnology is forging a new trend: the transformation of existing know-how into practical applications mainly through the development of university spin-off companies. These activities are demanding the development and implementation of a new IPR environment not seen before.

In continuation of the success obtained with the complete sequencing of *Xyllela fastidiosa* in 2000, a major genome effort has been launched by the Brazilian Government in the form of major network projects dealing with strategically chosen microorganisms and supported by the the Ministry of Science and Technology. Some examples are the sequencing of *Chromobacterium violaceum* by the Brazilian Genome National Network, *Paracoccidioides brasiliensis* by the West Central Network, *Schistosoma mansoni* by the Minas Gerais State Network, *Leishmania chagasi* by the Northeast Network, *Trypanosoma cruzi* and *Herbaspirillum seropedicae* Z78 by the Parana State Network, *Gluconacetobacter diazotrophicus* by the Rio de Janeiro State Network, *Crinipellis perniciosa* by the Bahia State Network and *Mycoplasma hyopneumoniae* by the South Genome Network. In the area of functional genomics and proteomics of

plants and animals, some of the on-going network projects, which involve many universities, Embrapa and, in some cases, the private industry, relate to the sequencing of banana (as part of the international consortium PROMUSA), eucalyptus, rice, coffee, guarana (a native Amazon species), soybean, maize, carrots, wheat, beans, bovine (as part of an international consortium) and nematodes.

The groundbreaking discoveries in genome research are creating the basis for understanding and exploitation of biological processes at the molecular level, opening up new paths for innovative processes. As it is expected that this enormous amount of new knowledge will, in time, generate innovative solutions and new products of greater aggregate value for the agriculture, health, nutrition and environment sectors, contractual rules should be established from the beginning to avoid later ownership problems. These rules should include confidential agreements for those having access to the databases, which should be negotiated with individuals receiving accession codes to the database, rules regarding the ownership of the information contained in the database as these are not directly patentable, but have a close link with the inventor of the supporting software, rules for ownership of products and processes to be potentially derived from the use of the databases and rules for return of royalties to the institution(s) providing germplasm, different combinations of breeding materials, molecular data, sequencing data and so on. When networking, it is also very important to make arrangements for publication procedures so as not to stop the flow of information but also not to publish before the right procedure has been taken regarding any protection opportunity.

Conclusions

One must be careful not to entangle different issues when discussing IPR. A balance must be found to give incentive to developing countries that can use new inventions as bargaining chips to access technology but at the same time attention should be given to guaranteeing rights to countries that are still lagging behind and are not, at present, in the position to use IPR as a development tool.

Faced with the present limited resources scenario, most R&D public institutions in developing countries, and mostly those in 'giant' developing countries such as China, India and Brazil, must still find a way to reach competitive results. One of the possible solutions is to guarantee return for the private sector investment in well-negotiated joint ventures. The most well-recognized tool for doing this, so far, is the use of IPR. In doing so, an R&D institution must review concepts starting from the design of the research project. According to data produced by WIPO (www.wipo.org), up to 70% of new scientific information is contained in

patent databases, making them a valuable and obligatory source of information to be checked when writing a grant proposal, in order to avoid duplication of effort and investment and to give researchers a clearer view of his/her research window. This is not yet a common practice in R&D institutions of developing countries.

On the same line, the free and informal exchange of research materials need to be preceded by a careful analysis of its legal implications, not only to protect opportunities, but also to avoid problems regarding infringement of third-party rights. Similar care should be given to any MTA to be signed by researchers, as a number of different models with different responsibility/liability clauses are beginning to proliferate and not everyone is aware of the implications. Very restrictive clauses to ascertain the ownership of newly developed varieties as a result of the incorporation of single genes patented by third parties can and should be carefully negotiated.

As the rules of the game will not change in the near future, researchers need to be taught the importance of a confidentiality agreement before explaining in detail his or her 'new invention'. There is always someone eager to listen!

On the international scenario, blaming the implementation of TRIPS for the lack of more funds for R&D in developing countries or even for the lack of funds to maintain gene banks – the repository of new genes – for further improvement of agricultural products, as seen in recent literature, does not uncover the entire picture. Both problems should be seriously and strategically resolved at the level of government, funding agencies and international donors if and when considered a priority to be supported for the benefit of mankind. Instead, developing countries with already established conservation capacity are being left to find their own resources as international priorities move on to other subjects. While this continues to happen, there will be less funding available or even political will to discuss and implement other pieces of legislation that interface with IP regarding for example farmer's rights (a new national responsibility coming from the FAO Treaty on Genetic Resources for Food and Agriculture) or the *sui generis* protection of traditional knowledge, which in Brazil is now a provision of the Access Law.

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