INTELLECTUAL PROPERTY PROTECTION FOR AGRICULTURAL BIOTECHNOLOGICAL INVENTIONS: A CASE OF MALAYSIA

Suzi Fadhilah Ismail, LLB., MCL

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Abstract

This research focuses on the current legal protection for agricultural biotechnological inventions in Europe and the U.S. It has been a subject of debate whether plants and agricultural biotechnological inventions which includes plants, transgenic plants and plant varieties, can be the subject of patent protection, in addition to or as an alternative to the protection afforded by plant variety rights. Biotechnological patents have been criticized for granting an excessive scope of protection to proprietors, whereas plant variety rights have been slighted for not providing enough protection. Hence, this research is built on a few main themes, namely; the discussion of IP protection for agricultural biotechnological inventions as currently in practice in Europe and the U.S., as well as the deliberation on the current system as practised in Malaysia. The research also discusses the issue of the interface between the patent regime and plant variety rights over agricultural biotechnological inventions as there are possible overlaps between the two systems, notwithstanding the exclusivity of protection of plant varieties under the PVR system.

The research looks at the prospect for Malaysia as a developing country to enhance its current IP framework and legislation in order to develop its agricultural biotechnology industry. Hence, it focuses on whether there is a single system as a model of IP regime to be adopted by Malaysia in order to provide the best IP protection for its agricultural biotechnology industry. The comparative approach is inevitable, in referring to the European model and the American model as a guide. The relevant factors such as the different setting, society and economic strength are given due consideration in coming up with the proposal to amend the current intellectual property law and legal system in Malaysia. At the end, the thesis puts forward a model for Malaysia to further develop its system.

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Abbreviations and Acronyms

CBD	Convention of Biodiversity
DNA	Deoxyribonucleic Acid
DOA	Department of Agriculture
DUS	Distinct Uniform and Stable
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FRIM	Forest Research Institute of Malaysia
MARDI	Malaysian Agricultural Research and Development Institute
MCB	Malaysian Cocoa Board
MPOB	Malaysia Palm Oil Board
MRB	Malaysian Rubber Board
MyIPO	Malaysian Intellectual Property Office
PBR	Plant Breeders' Right
PCT	Patent Cooperation Treaty
PLT	Patent Law Treaty
PPA	Plant Protection Act
PVP	plant variety protection
PVPA	Plant Varieties Protection Act
R&D	Research and Development
RI	Research Institute
TRIPS	Trade Related Aspects of Intellectual Property Rights
UPA	Utility Patent Act
UPOV	International Convention for the Protection of New Varieties of Plants
USPTO	United States of Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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Chapter 1

Introduction

1.1 Agricultural biotechnology: An overview of current developments

1.1.1 Biotechnology in general

Biotechnology is not a new science. It is based on very old traditions used since the beginning of the civilized world to improve products of the land such as agricultural products and animal farming.[1] The origin of biotechnology can be traced back to prehistoric times, when microorganisms were already used for processes like fermentation. Beer brewing, cheese making and production of sour milk are some of the common examples which are often included in describing what is called biotechnology.

The term 'biotechnology' generally refers to the use of biological processes, as through the exploitation and manipulation of living organisms or biological systems, in the development or manufacture of a product or in the technological solution to a problem. As such, biotechnology is a general category that has applications in pharmacology, medicine, agriculture, and many other fields. In relation to genetic engineering, the techniques have been used to manipulate the deoxyribonucleic acid (DNA) of bacteria and other organisms to manufacture biological products such as drugs. Plants and foods with desired qualities such as prolonged shelf life or increased resistance to diseases and pests have been created through genetic engineering; that is, by inserting DNA from other organisms.[2]

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[1] GREAVES, ROSA, 1991. Biotechnological Inventions. *In :* GREAVES, Rosa, ed. *Protecting and Exploiting Biotechnological Inventions.* Chur,Switzerland : Worldwide Information Inc. p. 5.

[2] R. W. Old and S. B. Primrose, 1994. Principles of Gene Manipulation ; J. E. Smith, Biotechnology 1996. *Columbia Encyclopedia* [online], Available at : <URL:http://www.answers.com/topic/biotechnology?cat=health>[Accessed 04 December 2007]

1.1.2 Plant biotechnology

In the context of the modern biotechnological revolution, plant genetic resources have become a significant source for plant breeding, crop development and enhancement.[3] Undoubtedly, like most technology, biotechnology can be used for good or ill, but in the field of agriculture, it has the prospect of giving enormous benefits in the quality and yield of foods and the range over which they can be grown.[4] The advent of genetic engineering has permitted the expeditious introduction of a wide range of desirable traits into plants. These include: pest control traits such as insect and virus resistance as well as herbicide tolerance; post-harvest traits such as delayed ripening of spoilage prone fruits; male and/or seed sterility for hybrid systems; and output traits such as plant colour and vitamin enrichment.[5] Despite the fact that some people have been opposing and viewing biotechnology with caution, the remaining section of the public is attracted to the benefits of biotechnology for food, for example as evidenced by the demand for *Falvr-savr* tomatoes, that is a new variety of tomatoes which remain ripe far longer than normal tomatoes before they rot after their introduction in the United States.[6]

Biotechnology has taken the development of new plants and seeds into the fast lane.[7] The world is experiencing a 'breakthrough in agricultural technology that may soon enable us to harvest crops from deserts, farm tomatoes in sea

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[3] The work of Brush, S. (see BLAKENEY, Michael, 2001, Intellectual Property And Agriculture : The Issue Of Biotechnology. *In :* MCMAHON, Joseph A., e. *Trade & Agriculture : Negotiating A New Agreement?.* London : Cameron May Ltd. p. 350.

[4] NOTT, Robin, 1995. The Biotech Directive: Does Europe Need a New Draft?. *E.I.P.R.,* 12, pp. 563-567, at p. 563.

[5] The work of Linder (see BLAKENEY, Michael, 2001, Intellectual Property And Agriculture : The Issue Of Biotechnology. *In :* MCMAHON, Joseph A., e. *Trade & Agriculture : Negotiating A New Agreement?.* London : Cameron May Ltd. p. 350)

[6] NOTT, Robin, *op.cit.,* Note 4.

[7] *The Economist,* 27 September 1986, at 82. (see CHRISTIE, Andrew, 1989. Patents for Plant Innovation. *E.I.P.R.,* 11, pp. 394-408)

water, grow super potatoes in many new localities, and enjoy entirely new crops such as *pomato*. We can now isolate and manipulate the genes that constitute the hereditary materials of each species' genetic makeup.'[8] These recent developments in biotechnology have increased the need to protect inventions and regulate commercial exploitation.

1.1.3 Legal mechanism: Protection via patent and plant variety rights

The most important mechanisms for legally protecting agricultural biotechnological inventions are patents and plant variety rights. It has been a subject of debate and a matter of dispute whether plants and agricultural biotechnological inventions can be the subject of patent protection, in addition to or as an alternative to the protection afforded by plant variety rights. Biotechnological patents have been criticized for granting an excessive scope of protection to proprietors, whereas plant variety rights have been slighted for not providing enough protection.[9] This issue is 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.[10]

The possibility of patent protection for plants and animals was first mooted at about the beginning of the 20th century. However it was a long time before this view was accepted by legislatures, courts and Patent Offices.[11] This is due to the belief that living organisms and cells were non-patentable products of nature. Hence, under the rationale that naturally occurring organisms were not

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[8] The work of Norman (see MARIN, Patricia L.C., 2002, *Providing Protection for Plant Genetic Resources: Patents, Sui Generis Systems, and Biopartnerships.* New York : Kluwer Law International. p. 4)

[9] The work of Roberts and Royon (see FUNDER, Joshua V., 1999. Rethinking Patents for Plant Innovation. *E.I.P.R.,* 11, 551-574 at p. 567.)

[10] CRESPI, R.S., 2004. European Union. *In:* ERBISCH, Frederick H., ed. *Intellectual Property Rights in Agricultural Biotechnology.* Cambridge: CABI Publishing. p. 261.

[11] NOTT, Robin, 1992. Patent Protection for Plants and Animals. *E.I.P.R.,* 3, pp. 79-86 at p. 79.

new, the assumption was that patents could not be granted. In such a case, it was perceived that the grant of a patent would remove from the public domain something 'which nature has produced and which nature has intended to be equally for the use of all men'.[12]

The issue of the patenting of life-forms was finally given a judicial answer in the landmark decision of the United States Supreme Court in 1980 in *Diamond v Chakrabarty.*[13] It was held that a bacterial strain into which a plasmid from another strain had been inserted constituted patentable subject-matter. The Court distinguished the products of nature from man-made inventions and held that statutory subject-matter included 'anything under the sun made by man' and that genetically engineered micro-organisms were not precluded from constituting patentable subject-matter merely because they were living cells. Although this clearly spelled out liberal approach, not many countries have followed up by clear permissive legislation. In fact, there are only a few specific exclusions in those jurisdictions, hence vagueness reins.[14]

Undeniably, intellectual property rights (IPRs) offer a temporary monopoly for the commercial exploitation of an invention and innovation, thus creating an incentive for further research and development. As patents primarily serve an economic function, the basic belief governing the system is the conviction that the protection provides an incentive for people to innovate and invest. Hence the possibility of recouping the high investment in genetic engineering and plant development industry can effectively be guaranteed through adequate

[12] WESTERLUND, Li, 2002. *Biotech Patents: Equivalency and Exclusions under European and US Patent Law.* The Hague : Kluwer Law International. p. 1.
[13] 206 USPQ 193 (1980).
[14] NOTT, Robin; *supra* Note 11, p. 80.

legal protection. This justification, though controversial, is equally legitimate from a public policy perspective. Nevertheless, the economic justification for patent is not always uncontroversial, as many IPRs, which include patent laws, have been asserted of going too far in protecting those who produce innovations at the expense of those who use them. Historically, and even today, the way patents have been justified in different countries has depended on the level of industrial development.[15] The use of IPRs in plant breeding especially in developing and least developed countries have raised issues on food security, smallholders' access to technology and the possible monopolization of genetic resources.[16]

Another related concern in developed countries is pertaining to the changes in the structure and composition of the plant breeding and seed industry, in particular the increasing involvement of large companies. The increasing role of the private sector in fundamental research has triggered the issue of the appropriate scope and system of protection for results of such research.[17] For example, Monsanto's decision to co-operate with plant breeders in the development of new plant varieties through the combination of traditional plant-breeding methods with its genetic resources aroused the question of the extent to which IPRs should be used to protect the results of genetic research.[18]

1.1.4 Global IPR regime

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[15] DUTFIELD, Graham, 2003. *Intellectual Property Rights and the Life Science Industries A Twentieth Century History.* Hampshire : Ashgate Publishing Limited. p. 2.

[16] BONADIO, Enrico, 2007. Crop Breeding and Intellectual Property in the Global Village. *E.I.P.R.,* 5, pp. 167-171.

[17] HEITZ, Andre, 1988. Intellectual Property in New Plant Varieties and Biotechnological Inventions. *E.I.P.R.,* 10, pp. 297-301.

[18] LLEWELYN, Margaret, 2000. The Patentability of Biological Material: Continuing Contradiction and Confusion. *E.I.P.R.,* 5, pp. 191-197.

As far as the global intellectual property regime is concerned, the most significant IPR treaties in the context of plants and biotechnological inventions are the Agreement on Trade-Related Aspects of Intellectual Property Rights (henceforward the TRIPS Agreement or TRIPS), and the Convention of the International Union for the Protection of New Varieties of Plants (The UPOV Convention). The former, which is administered by the Geneva-based World Trade Organization (WTO), is so important because it is the first and the only international treaty which seeks to establish enforceable universal minimum standards of protection for all the major intellectual property rights. The latter, which is administered by another intergovernmental organization, the International Union for the Protection of New Varieties of Plants (UPOV), is significant because it deals specifically with plant varieties.[19] These two treaties, together with regional treaties such as the European Patent Convention (EPC) and the European Directive on the Legal Protection of Biotechnological Inventions[20] (henceforward EU Directive 98/44) will be discussed in greater detail in Chapter 2 of this thesis.

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[19] DUTFIELD, Graham, 2000. *Intellectual Property Rights, Trade And Biodiversity.* London: Earthscan Publications Ltd., p. 8.

[20] Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions.

1.2 Scope of study

1.2.1 Research questions

This thesis is concerned with the issues surrounding the legal protection of agricultural biotechnological inventions. As far as inventions in agricultural biotechnology are concerned, they may be related to any of three types: methods, genes, or varieties. 'Methods' are techniques used in breeding or genetic manipulation. 'Genes' refer to biological information which mainly consists of isolated genes or proteins but also includes unicellular microorganisms such as bacteria, whereas 'varieties' generally refer to a specific hybrid of plant. This thesis will focus on the issues of legal protection for 'plant varieties' as they have attracted much debate and discussion on that particular area.

Among the primary questions that will be the central themes are the current legal protections available in European countries (EU) in particular in the United Kingdom (UK) for agricultural biotechnological inventions. The thesis will also scrutinize the various ways the laws relating to intellectual property rights have been interpreted in dealing with the issues of protecting the biotechnological inventions relating to plants and plant varieties in the UK. Besides, the thesis seeks to examine the advantages and disadvantages of the patent regime in comparison to plant variety rights in order to evaluate whether there is an interface problem as has been asserted by the protagonists of patents and plant variety rights.

Most importantly, the thesis is aimed at answering the main question for the whole research, that is to propose the best way to protect agricultural biotechnological inventions in Malaysia, taking into account the relevant factors such as the much slower development of biotechnological inventions relating to plants compared to the development in the UK, the different nature of farming activities, economic strength, and so forth. In other words, it is vital to ascertain the extent and ways the intellectual property laws in the UK relating to agricultural biotechnological inventions that would be relevant and significant to shape and improve the current laws in Malaysia.

1.3 Methodology

The methodology that will be applied to the whole research is a mixture of black-letter approach and qualitative approach. The black-letter or doctrinal approach is inevitable in order to analyze the international treaties such as TRIPS and the International Convention for the Protection of New Varieties of Plants (UPOV), regional treaties under the EU such as the European Patent Convention (EPC) and EU Directive 98/44, national laws such as the UK Patents Act 1977, the UK Plant Varieties Act 1997, the US Plant Patent Act 1930, the US Plant Variety Protection Act 1970 (as amended in 1994), the US Patent Act 1952, the Malaysian Patent Act 1983, the Malaysian Protection of New Plant Varieties Act 2004 and so forth, as well as a number of decided cases on the issue of agricultural biotechnology. The doctrinal approach is appropriate and proves to be the best way to produce legal analysis of the relevant treaties, conventions, statutes, and case-law which form an important part of this thesis.

On top of that, the qualitative approach also forms a significant component of the thesis. The empirical study will be in the form of a semi-structured interview and meetings that will be conducted at various agencies, bodies and research institutes in Malaysia which are involved in agricultural biotechnology industry. At this juncture, it is worth noting that "semi-structured interview" refers to a flexible method of interview, in which it allows new questions to be brought up during the interview as a result of what the interviewee says. This is opposed to a structured interview which is more formalized and has limited set of questions. As far as the research is concerned, the interviewees which have been selected, in fact, representing a large component of the agricultural biotechnology industry, and would be directly affected by whatever laws which are enacted and implemented in Malaysia. This empirical aspect of the research is vital because it would demonstrate the views as to the appropriateness and effectiveness of the systems available to the researchers and plant breeders in agricultural biotechnology. Besides, it seeks to explore the existing impediments, issues and problems encountered by the industry players especially in the area of research and development of the agricultural biotechnology sector. The study is justified to eventually meet the changing needs of those engaged in research and development of the agro-biotechnology that ultimately would further boost the growth of the industry in Malaysia.

1.4 Division of chapters

(i) Chapter 1

The first Chapter is an introduction which highlights the current debate and issues surrounding the legal protection of agricultural biotechnological inventions, in parallel to the advent in biotechnology relating to plants. The chapter describes the methodology applied for the whole study which consists of doctrinal and empirical research. It also seeks to define and clarify the legal terminologies which are used throughout this thesis. The definition and interpretation is vital in the sense that there have been much confusion and uncertainties over their intended or applicable meaning. Among the terminologies or phrases that will be dealt with in detail are the concept of agriculture, the meaning of the word "invention" as opposed to discovery in relation to patent law, definitions of biological process, microorganism, plant, plant breeders, plant variety, seeds, transgenic plant and so forth. The various ways of interpreting the above terminologies is apparently one of the main reasons for different approaches for awarding patents in various jurisdictions like the UK, the U.S. and developing countries which include Malaysia.

(ii) Chapter 2

This chapter looks at the international and European background in relation to legal protection of agricultural biotechnology. In particular this chapter concentrates on the laws relating to plant and animal varieties as provided under UPOV. Breeders' rights under UPOV will be analyzed from explanatory theoretical basis relative to the development that has taken place right from its inception in 1961 until the revision in 1972, 1978 and 1991. It is interesting to note that most, if not all, plant variety rights around the world are generally based on the UPOV Convention. The scope of protection and the issue of 'double protection' will be given special emphasis as they form the essence of the provisions. This thesis further brings into focus the scenario of European patent regime under the two relevant sources of patent law in Europe namely the EPC and EU Directive 98/44. The EPC plays an important role as it forms the basis of national laws within Europe leading to the current situation whereby plant varieties are, for the most part, considered non-patentable subject-matter protected only under a specialized plant breeders' rights form of protection. Most of the debates revolve around Article 53(b) of the EPC which excludes plant and animal varieties and essentially biological processes from patentability, even though it restores patentability to microbiological process and the products thereof. The issue will be specifically analyzed as it is an exclusion from the general possibility of patenting technological inventions and only concerns the biotechnological field.

Chapter 2 will also discuss the role of the Directive 98/44 which was adopted by the European Parliament and the Council of the EU in harmonizing the national laws of EU Member States relating to the protection of biotechnological inventions. The Directive, being an EU instrument, was not directly applicable to the EPC, although it is apparent that the European Patent Office (EPO) has adopted its main provisions as regard plant patenting. The Directive 98/44 in fact was not free from controversy after its entry into force, to the extent that it was even challenged for annulment by some of its Member States. The question whether the Directive is consistent with the international obligations of the Member States will also be considered in this chapter.

For the purpose of this study, the UK being one of the member states of EU will be taken as a case study, representing the legal scenario and application of patent regime and plant variety rights in relation to agricultural biotechnology in Europe. The reason lies on the fact that Malaysia's patent laws and practice are very similar to those of EPC and the UK. In other words, the Malaysian Patent Act 1983 has traces of similarity with the UK Patents Act 1977. It is pertinent to note at this juncture that Malaysia is lacking case law in the area of patents in particular and intellectual property in laws in general, hence the UK cases as well as cases decided by the EPO are highly influential and beneficial in interpreting Malaysian provisions. The practice of the EPO and the examination guidelines are equally useful in the sense that the EPO and WIPO have been helping the Malaysian intellectual property office (MyIPO) in training and formulating the examination guidelines. Besides, as a developing country, there is always a need for Malaysia to base its law and legal system on the much more developed legal systems. In this regard, the current UK intellectual property law would be taken as a model law subject to Malaysian variations wherever appropriate. The U.S. system of protecting plant related inventions is also relevant to provide a comparative approach of the legal scenario, taking into consideration the differences in terms of economic strength, the pace of biotechnological industry, the nature of farming activities and so forth.

Chapter 2 will also focus on TRIPS which was concluded along with and forming part of the Agreement of WTO. It is significant for setting the standards for IPRs far above those existing under other international treaties and conventions on intellectual property, which are mainly administered by the World Intellectual Property Organization (WIPO). The negotiation history which has paved the way to TRIPS will also be dealt with, with special emphasis on Article 27 of the TRIPS Agreement. It is important to note that TRIPS has been perceived by the developing countries as a new way of domination by developed countries over them. This controversy will also be considered and examined in this chapter.

The issue of the interface between patent and plant variety rights over agricultural biotechnological inventions is another important part of Chapter 2. The analysis as to where possible overlaps between the two systems may exist is scrutinized from the aspects of differences and similarities of these two regimes. It is important to note that the issue is relevant notwithstanding the exclusivity of protection of plant varieties under the PVR system, as the European legal framework is far from drawing a clear demarcation line between the systems of protection. [21] The last part of Chapter 2 is an analysis and review of some of the selected case law which have been decided on the issue of patentability of plants and agricultural biotechnology. Among the cases that will be examined in detail are *Ciba-Geigy*[22], *Lubrizol Genetic Inc.*[23], *Plant Genetic Systems*[24] and *Novartis*.[25] These cases are given paramount consideration in the sense that they are the landmark cases which delineate the approach adopted by EPO interpreting the Article 53(b) EPC on the exclusions of plant varieties from patentability.

(iii) Chapter 3

This chapter looks at the United States' approach in protecting agricultural biotechnological inventions. The fact that the U.S. has never excluded biological material and plant varieties from the scope of patentable subject matter will serve as a comparative approach for the purpose of this thesis, other than the EU's approach as elaborated in Chapter 2. It is interesting to note that the U.S. adopts a unique three-tiered system approach which never

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[21] MOUFANG, Rainer, 2003. The Interface Between Patents and Plant Variety Rights in Europe. Paper presented at *WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology, Geneva October 24 2003.* [online], Available at :
<URL:http://www.upov.int/en/documents/Symposium2003/wipo_upov_sym_06.pdf>[Accessed 06
December 2007]

[22] *Ciba-Geigy/Propagating Material* (Case T-49/83) [1984] OJ EPO 112. Also available at: < http://legal.european-patent-office.org/dg3/biblio/t830049ep1.htm> [Accessed 09 September 2008]

[23] *Lubrizol/Hybrid Plants* (Case T-320/87) [1990] OJ EPO 71. Also available at: <http://legal.european-patent-office.org/dg3/biblio/t870320ep1.htm> [Accessed 10 September 2008]

[24] *Plant Genetic Systems/Glutamine synthetase inhibitors (Opposition by Greenpeace) T356/93* [1995] EPOR 357; OJ EPO 545. EPO 545. Also available at: <http://legal.european-patent-office.org/dg3/biblio/t930356ep1.htm> [Accessed 11 September 2008]

[25] *Novartis/Transgenic Plant* (Case G01/98) [2000] EPOR 303; [1999] EPOR 123. Available at: < http://legal.european-patent-office.org/dg3/pdf/g980001ep1.pdf> [Accessed 25 September 2008]

places any restriction on the potential use of any regime of protection. This in effect dispenses with any potential overlap between different regimes of protection for plant varieties. In the U.S., plant varieties can be protected under a specific plant patent or under a system of utility patents or under the Plant Variety Protection.[26] This approach which differs from many other parts of the world in protecting newly developed plant varieties is perceived to contribute to the booming agribusiness industry in the U.S. Because of the influence of U.S. intellectual property law and cases on the most parts of the world, whether directly or indirectly, the three-tiered system approach in protecting agricultural biotechnology including some leading cases and recent development will be considered in detail in this chapter.

(iv) Chapter 4

This chapter in turn looks at the legal scenario of IPRs for biotechnological invention in Malaysia. The primary pieces of legislation are the Patent Act 1983 and the Protection of New Plant Varieties Act 2004. The relevant provisions from these two statutes will be discussed, notwithstanding the fact that the latter is relatively new and yet to be tested in any case law. Another important component of Chapter 4 is the insights of the latest development of agricultural biotechnology in Malaysia which include the current government's policy in actively promoting biotechnology research and development with the aim to attract investment for the industry as well as to enhance the local biotechnology. This is evident from the fact that the government has launched its Bio-Valley Project in 2003 and has produced the National Biotechnology

[26] TORREMANS, Paul, 2001. Plant Varieties And The TRIPs Agreement : Time For A Revision?. *In :* MCMAHON, Joseph A., e. *Trade & Agriculture : Negotiating A New Agreement?.* London : Cameron May Ltd. p. 96.

Policy in 2005, supported with a huge allocation of fund under Ninth Malaysia Plan (2006-2010) for the development of biotechnology in Malaysia.

(v) Chapter 5

The empirical part of this thesis which is incorporated in Chapter 5 consists of studies on related bodies, agencies and companies in Malaysia which have direct involvement with agricultural biotechnology. These include Malaysian Biotechnology Corporation (BiotechCorp), Plant Varieties Office at the Department of Agriculture (DOA), Intellectual Property Corporation of Malaysia (MyIPO), Malaysian Agricultural Research and Development Institute (MARDI), Forest Research Institute of Malaysia (FRIM), Malaysian Rubber Board (MRB), Malaysian Cocoa Board (MCB), and Malaysian Palm Oil Board (MPOB). The report and analysis of the data, information and statistics obtained from the study in the form of semi-structured interviews are incorporated in this chapter. The main focus of the study is to examine the current practice of the agricultural biotechnology industry and to address the issues such as; whether the plant related invention is adequately protected under the intellectual property laws in Malaysia and to what extent there is a need of an improved legal system in Malaysia. The general headings under which the information obtained from the study are aimed to cover the plant breeding activities, type of intellectual property used, general levels of use, awareness and satisfaction with the protection, research and development activities, the ideal legislation[27] and current issues relevant to the study. This study is aimed as an indicator of the general view held across the agricultural biotechnology industry in Malaysia.

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[27] A similar study has been carried out in EU. Refer LLEWELYN, Margaret and ADCOCK, Mike, 2006. *European Plant Intellectual Property.* Oxford : Hart Publishing. p. 440.

(vi) Chapter 6

This Chapter incorporates a comprehensive and detailed discussion in a form of proposal, which is geared towards a better intellectual property laws in Malaysia. The proposal is based on the assessment of the study in Chapter 4 and 5 as well as the essence of current practice in the UK and the U.S. in Chapter 2 and Chapter 3 respectively. It is vital to have a balanced approach by weighing pros and cons in order to create an enabling environment in Malaysia. The ultimate aim of this thesis is to propose a law and a viable system which best suits the need of agricultural biotechnology scenario in Malaysia. The answer could lie in the middle-ground approach which is the harmonization of patents and plant variety rights. Whatever the outcome is, justification and policy consideration would be given paramount consideration in parallel to the practicality and the viability of the legal protection for the agricultural biotechnological inventions in Malaysia.

(vii) Chapter 7

The final Chapter is a concluding chapter which reiterates and summarizes all the six preceding chapters of the whole thesis, with an emphasis on the thesis outcome. Most importantly, it highlights the contribution and fruit of the research which has been dedicated throughout the whole duration of the study, with the main aim of enhancing the current IP legal system in Malaysia, towards global harmonization ultimately.

1.5 Defining the Terminology

At first glance, the topic of the research would appear to be straightforward and not at all complicated. The complexity arises in relation to some of the terminology and concepts which have no universal definition, yet will be utilized throughout the writing of this thesis. Hence, it is essential to provide at the very outset a sufficiently clear literal and legal definition to the terminology wherever possible. The following terminology will be addressed in turn.

(i) Agriculture

(ii) Biological process, microbiological process

(iii) Genetic engineering

(iv) Invention (as opposed to discovery)

(v) Patent

(vi) Utility models for innovation

(vii) Plant, plant variety, crops, seed

(vii) Plant variety rights, plant breeders' rights, farmers' rights

(viii) *Sui generis* protection

It is worth mentioning at this juncture that the definition and interpretation for the above terminology would be discussed and enunciated in reference to relevant statutes, treaties, directives, case law, legal dictionaries, encyclopedias and common usage in the legal fraternity. The interpretation from a scientific point of view will also be given due consideration as the topic of this research is to some extent closely related to the advances in science and technology, in particular biotechnology.

(i) Agriculture

Most of the dictionaries[28] and encyclopedias[29] basically define the term 'agriculture' as the art and science of cultivating the soil, growing and harvesting crops, and raising livestock. In the context of modern agriculture, the era of mechanized agriculture began with the invention of such farm machines as the reaper, the cultivator, the thresher, and the combine. Harvesting operations have been mechanized for almost every plant product grown. Breeding programs have developed highly specialized animal, plant, and poultry varieties, thus increasing production efficiency. The development of genetic engineering has given rise to genetically modified transgenic crops and, to a lesser degree, livestock that possesses a gene from an unrelated species that confers a desired quality.[30]

In short, the phrase 'agricultural biotechnological inventions' in this thesis refers to all forms of invention and development relating to plant life. This, of course, includes the creation of new plants, such as plant genetic material, transgenic plants as wells as the techniques or process for creating new plants and such material. As the focus of the research is on plants and crops, it would not cover animals or animal varieties, notwithstanding the fact that livestock forms part of the general definition of agriculture. This is justifiable from the context that most of the debates on this area revolve around the adequacy and efficiency of the legal protection over plants and the related inventions.

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[28] GARNER, Brian A., Ed., 2004. *Black's Law Dictionary.* 8th ed. United States : Thomson West. p. 75.

[29] Refer *Britannica Concise Encyclopedia, Columbia Electronic Encyclopedia, McGraw-Hill Encyclopedia of Science and Technology & Wikipedia*. Available at : <URL : http://www.answers.com/topic/agriculture?cat=technology> [Accessed 08 January 2008]

[30] ANON., 2003. *The Columbia Electronic Encyclopedia*. 6th ed. Columbia : Columbia University Press.

(ii) Biological process, microbiological process

It is essential to distinguish the meaning and interpretation of these two scientific terms literally and legally. The issue of the interpretation of these two terms initially stems from the provisions of Article 27(3)(b) of the TRIPS Agreement and Article 53(b) EPC which spell out the exclusions from patentability on certain living organisms.

Article 27(3)(b) TRIPS Agreement says that: 'Members may also exclude from patentability: plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes...'

Article 53(b) EPC 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; this provision does not apply to microbiological processes or the products thereof.'

Similar exclusions from patentability have been adopted in various national statutes, *inter alia,* Section 76A (Schedule A2) of the UK Patents Act 1977 and Section 13(1)(b) of the Malaysian Patents Act 1983. Apparently, Article 53(b) EPC and Article 4(1) of the EU Directive 98/44 incorporate similar exclusions on patentability for biological processes.

Literally, biological process refers to a process relating to biology or life.[31] Hence, a process for the production of plants or animals is 'essentially biological' if it consists entirely of natural phenomena such as crossing or

[31] GARNER, Brian A., *supra* Note 28. p. 178.

selection.[32] The term 'microbiological process' is succinctly defined by Article 2 EU Directive 98/44 and the UK Patents Act (Schedule A2) to mean any process involving or performed upon or resulting in microbiological material. The same definition is found in the Rule 23b(6) of the Implementing Rules EPC.

It is important to distinguish between these two terms and concepts, as the former would result in the exclusion from patentability, while the latter is legally patentable under the various legislations as enunciated above. As the value of a patent is in the protection it confers, this issue is very fundamental in this field. One of the examples in which the term 'microbiological process' was expounded is the case of *Plant Genetic Systems.*[33] It was held that microorganisms could be patentable, being the products of microbiological processes, and were defined as 'generally unicellular organisms with dimensions beneath the limits of visions which can be propagated and manipulated in a laboratory' which did include viruses and plasmids.[34] Nevertheless, the above case of *Plant Genetic Systems* has been overtaken by another landmark case, *Novartis*, which will be discussed in detail in Chapter 2.

Although a number of decisions[35] by the EPO Technical Board have addressed the exceptions to patentability in the context of genetically engineered life forms, there is no clear demarcation line yet between what is to be considered a patentable 'microbiological' process and a non-patentable 'essentially biological' process. Further, since there are no binding definitions to show a

[32] Article 2 (2) EU Directive 98/44; Section 76A (Schedule A2.11) UK Patents Act 1977.
[33] *Supra*, Note 6.
[34] SCHERTENLEIB, Denis, 2004. The Patentability and Protection of Living Organisms in the European Union. *E.I.P.R.,* 5, pp. 203-213, at p. 203.
[35] For example, Plant Genetic Systems/Glutamine Synthesis Inhibitors (Case G-3/95)[1996] OJ EPO 169; (Case T-356/93)[1995] EPOR 357.

clear-cut distinction between these two terms in the EPC, the potential for differing interpretations and applications persists among the various member nations' courts.[36] It is interesting to note that there have been related issues which have attracted considerable debate and discussion on this point, *inter alia*, where is the exact point of demarcation between a plant cell regarded in patent law as a micro-organism and therefore patentable, and a plant cell which may be excluded from protection?[37] On a more theoretical level, it has become clear that there is no clear scientific line between biology and micro-biology, rendering the whole meaning of the distinction between non-patentable biological processes and their patentable microbiological counterparts opaque and difficult to operate.[38]

In addition, on the issue of patenting microbiological processes involving transgenic plants and plant varieties specifically, rule 23c of the EPC (Implementing Regulations) clearly states that the product of a microbiological process shall not be patentable if it is a plant or animal variety.

The fact that the language of Article 53(b) EPC is open to various interpretations has made the EPO at times struggle both internally to agree what the exclusion covers and externally to convince others that its approach is the correct one. For example in the case of *Plant Genetic Systems*,[39] the distinction drawn by the Technical Board between essentially biological and microbiological was unclear and did not pinpoint when a process would be said

[36] LICATA, Jane Massey, *Patenting Biotechnology Inventions in The European Patent Office*. Available at : <URL : http://www.licataandtyrrell.com/epopat.htm> [Accessed 09 January 2008]
[37] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. p. 293.
[38] CORNISH, W. and LLEWELYN, D., 2007. *Intellectual Property: Patents, Copyright, Trade Marks And Allied Right.* 6th ed. London : Sweet & Maxwell. p. 231.
[39] *Supra*, note 24.

to be no longer essentially biological.[40] A recent interlocutory decision of a Technical Board of Appeal in the case of *Plant Bioscience Limited* (T 83/05)[41] of the European Patent Office has been referred to the Enlarged Board of Appeal in order to define the boundaries for the exclusion from patentability established in Article 53(b) EPC. In this case, the Enlarged Board of Appeal is to decide whether or not the relevant method falls within the Article 53(b) exclusion. Among the questions which have been put to the Enlarged Board of Appeal is to decide on the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from the non-excluded ones. As at November 2010, this Enlarged Board of Appeal Decision was still pending under the reference number G 2/07.[42]

The apparent interface between the EPC and the EU Directive 98/44 in terms of their respective approach over patentability of transgenic plants will be dealt with in detail in the next chapter.

To sum up, as far as this thesis is concerned, based on the above discussion, the working definition for the following terms is:

- "biological process" is all processes which consist entirely of natural phenomena for the production of plants such as crossing and selection;
- "microbiological process" refers the relevant processes involving or performed upon or resulting in microbiological material (as expressly provided in the EU Directive 98/44 and the UK Patents Act 1977).

[40] LLEWELYN, Margaret and ADCOCK, Mike, *op.cit.,* p. 290-303.
[41] *Plant Bioscience Limited v. Sygenta Participations AG Groupe Limagrain Holding* T 0083/05 – 3.3.04 (Interlocutory decision of 22 May 2007).
[42] Mc Donald, Chris, 2007. *EPO May Exclude Essentially Biological Processes For Plant Production.* Available at: <URL: http://www.withersrogers.co.uk/content/view/134/45/> [Accessed 19 February 2008]

(iii) Genetic engineering

Genetic engineering refers to a method of creating new life-forms and organic matter by gene-splicing and other techniques.[43] The U.S. Supreme Court in the landmark case *Diamond v Chakrabarty*[44] has evidently ruled that those creations are patentable. Genetic engineering is usually done independently of the natural reproductive process. The result is a so-called genetically modified organism (GMO). To date, a substantial effort in genetic engineering has been focused on agriculture. Proponents of genetic engineering claim that it has numerous benefits, including the production of food-bearing plants that are resistant to extreme weather and adverse climates, insect infestations, disease, molds, and fungi.[45]

In relation to biotechnology, genetic engineering falls under the wide umbrella of biotechnology. This is due to the fact that biotechnology is a generic term which is used to cover a very broad field of study, which ranges from the many tools and techniques that are commonplace today in agriculture and food production, to the latest technologies, including gene manipulation, gene transfer, DNA typing and the cloning of mammals. With the rapidity of changes occurring in the sector, the terminology is constantly evolving, and yesterday's buzzword is today's jargon, and might be tomorrow's mainstream

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[43] GARNER, Brian A., *supra* Note 28. p. 707.
[44] *Supra* Note 13.
[45] Refer <URL:http://whatis.techtarget.com/definition/0,,sid9_gci1110323,00.html> [Accessed 10 January 2008]

term. The evolution of terminology has occurred so rapidly that it has been very difficult to remain abreast of its current usages.[46]

To recapitulate, the term genetic engineering refers to methods and processes to investigate the isolation, change and transfer of genetic material.

(iv) Invention (as opposed to discovery)

Black's Law Dictionary defines invention in the context of patents as a patentable device or process created through independent effort and characterized by an extraordinary degree of skill or ingenuity.[47] As far as the patent law is concerned, for an invention to be patentable, it must meet specific criteria and, in addition, not be explicitly excluded from patentability. As a matter of fact, only few countries have in their respective patent laws set forth a positive definition of the subject matter considered to be an invention under the legal concept.[48] The Malaysian patent law is an exception in this respect, stating that: 'An invention means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.'[49] The definition is very general and broad, which may cover inventions in the field of biotechnology.

The TRIPS Agreement provides no definition of an invention yet mandates that patent protection is equally extended to all technologies, including biotechnological inventions.[50] The EU Directive 98/44 stipulates the elaborated

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[46] Glossary of biotechnology and genetic engineering, 1999. *Sustainable Development Department, Food and Agriculture Organization of the United Nations (FAO)* [online] Available at: <URL:http://www.fao.org/sd/RTdirect/RTre0036.htm> [Accessed 10 January 2008]

[47] GARNER, Brian A., *supra* Note 28. p. 843.

[48] WESTERLUND, Li, *supra* Note 12. p. 24.

[49] Section 12(1) Malaysian Patent Act 1983.

[50] Article 27 paragraph 1 TRIPS Agreement provides that: 'Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application…'

characteristics of a patentable invention. Article 3(1) says that: 'For the purpose of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.' The difficulty of outlining a positive, precise legal definition of the invention concept explains why most patent laws do no include one.[51]

The principle is that patents cannot be granted for discoveries, as clearly spelt out in all patent laws, while at the same time biotechnological inventions consisting of gene sequences are patentable. For biological phenomena which to a certain extent 'exist in nature', the invention concept has somewhat been extended in order to accommodate these types of inventions like gene sequences, cell lines and the like.[52] The key distinction is well-known in many patent systems: discovery is the unearthing of causes, properties or phenomena already existing in nature; invention is the application of such knowledge to the satisfaction of social needs.[53]

One of the most frequently debated issues relating to the concept of patentable invention is whether inventions using plant material or transgenic plants are eligible for patent protection. The issue has attracted considerable debates and concerns specifically in Europe. This is attributed to the practice of the European Patent Office (EPO) which grants patent protection for inventions relating to processes and genetic materials used to create transgenic plants, but does not allow product claims to transgenic plants. The

[51] WESTERLUND, Li, *supra* Note 12, p. 25.
[52] *Ibid.* p.24.
[53] CORNISH, W. and LLEWELYN, D., *supra*, note 38. pp. 215-216.

EPO considers modification of a plant's genetic material equivalent to creating new plant variety, and the EPC expressly prohibits patenting plant varieties.[54] The EPC classifies plant varieties as non-patentable subject matter, even when the transgenic plants would otherwise satisfy the criteria for patentability, namely: novelty, inventive step and industrial utility. Although transgenic plants can be claimed using product-by-process claims, most applicants would prefer the stronger protection afforded by product claims to transgenic plants.[55] This issue will again be examined in greater detail in the next chapter.

In short, for the purpose of this thesis, the term 'agricultural biotechnological inventions' denotes all plant related inventions which may cover transgenic plants, as well as new plant varieties.

(v) Patent

Basically, patent is the governmental grant of a right, privilege, or authority.[56] In essence it is the grant of a monopoly to an inventor who has used his skill to invent something new. The monopoly is not absolute; patents are only granted for a limited period and are accompanied by public disclosure enabling others in the field to consider and perhaps subsequently improve on it. Patent has been the longest standing, best known and, arguably, economically most valuable form of protection of rights by the law of intellectual property.[57]

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[54] Article 53 (b) EPC.
[55] PERDUE, Donna O., 1999. The Changing Landscape for Patenting Transgenic Plants in Europe. *CASRIP Newsletter*, 6. [online] Available at: <http://www.law.washington.edu/Casrip/Newsletter/Vol6/newsv6i1Perdue.html> [Accessed 10 January 2008]
[56] GARNER, Brian A., *supra* Note 28. p. 1156.
[57] TORREMANS, Paul, 2005. *Hoalyak and Torremans Intellectual Property Law.* 4th ed. Oxford : Oxford University Press. p. 37.

Patent is generally granted over an invention if the invention is new, involves an inventive step and is capable of industrial application.[58]

As far as the international dimension is concerned, cries have been long heard clamouring for greater levels of harmonization in domestic patent law between trading nations. The idea of the establishment of a global patent system has raised the problem of whether worldwide patent law is ever likely to be feasible, given the different levels of development, innovatory capacity and legal systems found around the world. The culmination of harmonization of substantive patent law at the international level eventually took place when the TRIPS Agreement was signed, and the WTO being set up as a world trade organization whose competence includes aspects of intellectual property.[59]

The TRIPS Agreement imposes for the first time substantive minimum standards in patent law with which all WTO Member States have to comply. TRIPS defines the concept of patentable subject-matter broadly, on the basis that patent should be made available for any inventions in any field of technology, as long as the invention is new, involves an inventive step and is capable of industrial application.[60]

As far as the development in Europe is concerned, the search for a common European concept of the patent led to the signing in Munich in 1973 of the EPC which establishes the EPO which has, since 1978, offered to applicants a European Patent in effect. This is achieved by signatory states agreeing to

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[58] Section 1(1) UK Patents Act 1977; Section 11 Malaysian Patents Act 1983; Article 27(1) TRIPS Agreement.
[59] TORREMANS, Paul, *supra.,* Note 57. pp. 41-43.
[60] Article 27-34 TRIPS Agreement.

harmonize their own patent law with the definition in the EPC – hence the 1977 Patents Act in the UK – and the EPO then awarding patents in all Member States where the applicant has sought to acquire patent protection.[61] In the year 2000, the EPC has been revised with the aims amongst other things, to integrate in the EPC new developments in international law, especially those of the TRIPS Agreement and of the Patent Law Treaty. The European patent laws system will be dealt with in the next chapter.

Since the U.S. intellectual property laws on agricultural biotechnological inventions are also part of the discussion in this thesis (Chapter 3), it is pertinent to note that the U.S. has three types of patent in relation to patent law, that is a 'design patent', a 'utility patent' and a 'plant patent'. The difference between a design patent and a utility patent is that a design patent protects the ornamental design, configuration, improved decorative appearance, or shape of an invention. This patent is appropriate when the basic product already exists in the marketplace and is not being improved upon in function but only in style. For example, designer eyeglass frames and the original Coca-Cola bottles, would have all been protected with design patents. A U.S. design patent lasts for 14 years. [62]

A utility patent protects any new invention or functional improvements on existing inventions.[63] This can be to a product, machine, a process, or even composition of matter. For example, going from LED technology to OLED would call for a new utility patent. In this case the material of the light emitting diodes has gone from the synthetic material used in LEDs to organic

[61] TORREMANS, Paul, *op.cit.*, p. 44.
[62] Refer <http://www.uspto.gov/patents/index.jsp>
[63] *Ibid.*

material in OLEDs. Other examples would be a better carburetter, a new type of self-fastening baby's diaper or a new recipe. The life of a US utility patent lasts 20 years from the date of filing.

Plant patents may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.[64] It expires 20 years from the filing date of the patent application. The discussion on the U.S. utility patent and plant patent is dealt with in a considerable detail in Chapter 3.

To recapitulate, the term patent in this thesis denotes a bundle of exclusive rights granted by a state to a patentee for a fixed period of time in exchange for a disclosure of an invention.

(vi) Utility models for innovation

A utility model is an intellectual property right to protect inventions. This right is available in a number of national jurisdictions, which include Malaysia. It is very similar to the patent, but usually has a shorter term (often 6 or 10 years)[65] and less stringent patentability requirements. The rights conferred by utility model laws are very similar to those granted by patent laws, but are more suited, but not restricted to, to what may be considered as 'incremental inventions'. A utility model right can be obtained for example, for electronic circuits, machines, chemical products, foodstuffs, pharmaceutical products and so forth. Terms such as 'petty patent', 'innovation patent', 'minor patent', and

[64] *Ibid.*
[65] In Malaysia, the term of protection for a utility innovation is 10 years; refer Section 35(1) Malaysian Patents Act 1983.

‘small patent’ may also be considered to fall within the definition of ‘utility model’.

As far as the term of ‘utility model’ is concerned, there is no standard provision by WIPO for utility innovation. In Malaysia, a lesser extent invention can qualify as a utility innovation. It is an exclusive right granted for a ‘minor’ invention which does not required to satisfy the test of inventiveness as required of a patent. Hence, a utility innovation can be applied as long as it is new and industrially applicable. Under the Malaysian Patents Act 1983, ‘utility innovation’ refers to any innovation which creates a new product or process, or any new improvement of a known product or process, which is capable of industrial application, and includes an invention.[66] As far as the rights and procedures are concerned, a utility innovation is subjected to a substantive examination as a patent application.[67]

It is noteworthy that the UK, in contrast to Malaysian patent system, does not presently have a utility model system. In 2001 the European Commission started a consultation on the possibility of a Community utility model with the aim of harmonizing the existing utility model systems. Nevertheless, progress has not been reported. In 2005, the European Commission announced that it would withdraw its proposal for a (harmonizing) Directive on utility models.[68]

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[66] Section 17 Malaysian Patents Act 1983.
[67] Section 17A(1)&(2) Malaysian Patents Act 1983.
[68] The proposal was finally withdrawn on March 17, 2006, [2006] OJ C 64/3 of March 17, 2006. Refer : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:064:0003:0010:EN:PDF> [Accessed 16 June 2010]

Therefore, a harmonization of the national utility model systems is not on the European Union's agenda anymore.[69]

As a matter of fact, the road ahead for utility model protection seems to be a difficult one. This can be seen from the confusion which is rampant within the UK. There is no apparent consensus as to either the need for utility model protection nor its scope if adopted. The prevailing impression is one of uncertainty, and possible confusion, over the role utility model protection would play.[70]

In short, the term 'utility innovation' in this thesis refers to the right granted to an invention which satisfies the requirements of novelty and industrial application.

(vii) Plant, plant variety, crops, seed

Generally, plant is a living organism of the kind exemplified by trees, shrubs, herbs, grasses, ferns, and mosses, typically growing in a permanent site, absorbing water and inorganic substances through its roots, and synthesizing nutrients in its leaves by photosynthesis using the green pigment chlorophyll.[71] Scientifically, the term 'plant' refers to any organism in the kingdom *plantae*, consisting of multicellular, eukaryotic life form with six fundamental characteristics: photosynthesis as the almost exclusive mode of

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[69] KONIGER, Karsten, Registration without Examination: The Utility Model – A Useful Model?, Available at: <http://www.springer.com/cda/content/document/cda_downloaddocument/9783540887423-c2.pdf?SGWID=0-0-45-637512-p173878523> [Accessed 15 June 2010]

[70] LLEWELYN, Margaret, 1995. Proposals for the Introduction of a Community Utility Model System: A UK Perspective. *Web JCLI*, Available at: <URL: http:// www.ncl.ac.uk/~nlawww/articles2/llewel2.html> [Accessed 15 June 2010]

[71] STEVENSON, Angus, Ed., 2010, *Oxford Dictionary of English*. Oxford: Oxford University Press. [Oxford Reference Online http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t140.e0638140]

nutrition, essentially unlimited growth at meristems, cells that contain cellulose in their walls and are therefore somewhat rigid, the absence of organs of movement, the absence of sensory and nervous systems, and life histories that show alternation of generations.[72] In the context of patent laws, other than 'plant', another term which is very closely related to it is 'plant variety'. Plant variety is defined by some dictionaries[73] to basically mean a population of plants that differ consistently from the typical form of the species, occurring naturally in a geographical area. Scientifically, plant variety is a plant belonging to a taxonomic subdivision of a species consisting of naturally occurring or selectively bred populations or individuals that differ from the remainder of the species in certain minor characteristics.[74]

From the legal point of view, the definition of the term plant variety is provided in a number of laws, notably the legislation on plant variety protection. This is different for the term 'plant', as there are not many laws which enunciate its specific definition, except for Section 2 of the Malaysian Plant Variety Protection Act 2004. In this 2004 Act, plant is clearly interpreted to mean 'any living organism in the plant kingdom but excludes any micro-organism.' The lack of definition for the term plant could be attributed to the fact that it is a common, general term in nature. In contrast, there is a vast definition for the term 'plant variety' which to some extent reflects the significance of the development in agricultural biotechnology.

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[72]ANON., 2006. *Britannica Concise Encyclopedia.* Encyclopædia Britannica Inc., [online] Available at: <http://www.answers.com/topic/plant> [Accessed 15 January 2008] The similar definition is provided in other encyclopedias – Refer <http://www.answers.com/topic/plant?cat=biz-fin>

[73] For example, refer ANON., 1997. *Taylor's Dictionary for Gardeners*. US : Houghton Mifflin Company. Available at: <http://www.answers.com/topic/variety> [Accessed 15 January 2008]

[74] ANON., 2004. *The American Heritage Dictionary of the English Language*. 4th ed. US : Houghton Mifflin Company. Available at: http://www.anwers.com/topic/variety [Accessed 15 January 2008]

Article 1(vi) of the 1991 UPOV Act defines a plant variety as 'any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

(c) considered as a unit with regard to its suitability for being propagated unchanged.'

The above definition mirrors the definition provided by Article 5 of Regulation (EC) No 2100/94 (for the purpose of Article 2 EU Directive 98/44 on the concept of 'plant variety) as well as Rule 23b(4) of the Implementing Rules EPC. The National legislation has also adopted the same definition namely the UK Plant Varieties Act 1997 and Malaysian Plant Variety Protection Act 2004. However, the fact that apparently, specific terms with specific definitions have been used does not necessarily indicate that those terms have an agreed meaning and interpretation. The above criteria of plant varieties are in fact not entirely precise and may give rise to difficulties of interpretation.

It is worth noting at this juncture that the TRIPS Agreement does not provide any definition as to what is a plant variety, with the impression that this is a recognized concept with a single meaning common to both science and law.[75] There is in fact no universal definition of what is a plant or a plant variety, and this is exemplified by the continuing discussions over *inter alia*, whether fungi

[75] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. p. 290.

are plants or micro-organisms, and whether one single stable gene within a grouping of plants is sufficient to warrant those plants being considered as a variety for a plant variety right purposes. [76] The distinction of 'plant' and 'plant variety' is very crucial from the legal point of view, as the former is generally patentable provided all the conditions are fulfilled under the patent law, whereas the latter is excluded from patentability, but is protected under UPOV or any *sui generis* system. This has been the legal position and practice in Europe, under Article 53(b) EPC. An extensive discussion on the European patent laws and the latest legal development will be dealt with in the next chapter.

The question of what constitutes a plant variety can be seen in a number of cases which came under the scrutiny of the EPO. For example, in the case of *Plant Genetic Systems,*[77] the Technical Board of Appeal EPO considered the definition of plant variety. The Board referred to earlier cases of *Ciba Geigy*[78] and *Lubrizol*[79] cases and confirmed the definitions used in both, namely; a variety is a 'multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle.'[80]

Some other related terms to plant are 'crop' and 'seed'. Crop is a general term which refers to a plant that is cultivated for the purpose of harvesting its seed, roots, leaves, or other parts that are useful to human.[81] Hence, in agriculture,

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[76] *Ibid*., p. 121. and pp. 300-301.
[77] *Supra*, Note 24.
[78] *Supra*, Note 22.
[79] *Supra*, Note 23.
[80] [1995] EPOR 357 at para 21.
[81] DAINTITH, John and MARTIN, Elizabeth,. 2010. Dictionary of Science, 6th Ed., Oxford : Oxford University Press, p. 205.

a plant or plant product that can be grown and harvested extensively for profit or subsistence is called crop.[82] In this sense, the term 'crop' is utilized in more specific context like the production of plant for the purpose of harvesting and cultivating.[83]

The other term, 'seed' is literally defined as the grains or ripened ovules of plants used for sowing.[84] Propagation of plants by seed and technological use of seed and seed products are among the most important activities of modern society. In the context of seed industry, the term denotes activities in breeding, developing, growing and commercializing seed.[85] As far as this thesis is concerned, it would also cover the biotechnological inventions in relation to seed, as 'seed' itself falls under the wide coverage of plants and agriculture.

In conclusion, for the purpose of this thesis, the working definition for the abovementioned terms is as follows:

- "Plant" refers to any living organism in the plant kingdom but excludes any micro-organism.
- "Plant variety" denotes a taxonomic subcategory of a species within the plant kingdom that has its own distinct recognizable characteristics irrespective of whether it is eligible for a grant of plant breeders' rights or not.

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82 ANON., 2006. *Britannica Concise Encyclopedia.* [online] Encyclopædia Britannica Inc., Available at: <URL:http://www.answers.com/topic/crop> [Accessed 16 January 2008]

83 Refer *Cambridge Dictionaries Online,* Available at : <URL:http://dictionary.cambridge.org/define.asp?key=18433&dict=CALD> [Accessed 16 January 2008]

84 Refer *Merriam-Webster Online*, Available at <URL:http://www.m-w.com/dictionary/seed> [Accessed 16 January 2008]; the similar definition can be found in other dictionaries and encyclopedias, refer *American Heritage Dictionaries, Britannica Concise Encyclopedia, Columbia Encyclopedia*, *supra* Note 2.

85 International Seed Federation, Refer <URL:http://www.worldseed.org/en-us/international_seed/home.html> [Accessed 16 January 2008]

- “Crop” means a plant grown and harvested extensively for profit or subsistence.
- “Seed” refers to the vegetative propagating material for the reproduction of a plant.

(viii) Plant variety rights, plant breeders’ rights, farmers’ rights

Plant variety rights (PVR) which are also known as plant breeders' rights (PBR) are fundamentally a bundle of rights granted to the breeder of a new variety of plant. PVR may subsist on varieties of all plant genera and species.[86] ‘Breeder’ is legally defined as the person who bred, or discovered and developed, a variety, the person who is the employer of the aforementioned person or who has commissioned the latter’s work, where the laws of the relevant Contracting Party so provide, or the successor in title of the first or second aforementioned person, as the case may be.[87] For the purpose of this thesis, the terms PVR will be used.

This legal protection of plant varieties was initially established in the late 1950s in a number of countries and eventually regulated at the international level of the ‘International Union for the Protection of New Varieties of Plants’ (the UPOV[88] Convention of 1961). The main motivation for devising the special PVR system was that the long-established patent system, intended for the protection of technical inventions was for various reasons not considered suitable for protecting new plant varieties obtained by traditional methods.[89] In this sense, the PVR regime was designed to give the traditional plant

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[86] Section 1(2) UK Plant Varieties Act 1997.
[87] Article 1(iv) UPOV 1991.
[88] The French language acronym for the International Union for the Protection of New Varieties of Plant.
[89] The Chartered Institute of Patent Attorneys (CIPA), Intellectual Property Protection for New Plants, Available at <URL:http://www.cipa.org.uk> [Accessed 06 December 2007]

breeders an increased incentive to develop new varieties while respecting their traditions of exchanging material.[90] The system was set up by plant breeders for plant breeders hence it forms one of the unique facets of PVR.[91]

The scope of the breeder's right is spelt out in Article 14(1)(a) of the UPOV 1991. The Article says that: 'Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

(i) production or reproduction (multiplication),

(ii) conditioning for the purpose of propagation,

(iii) offering for sale,

(iv) selling or other marketing,

(v) exporting,

(vi) importing,

(vii) stocking for any of the purposes mentioned in (i) to (vi), above.

The above provision is incorporated in the UK Plant Varieties Act 1997 (Section 6(1)), as well as the Malaysian Protection of New Plant Varieties Act 2004 (Section 30(1)). Another important aspect of PVR is the conditions for the grant of the rights. In order to qualify for protection, a variety must be new, distinct, uniform and stable[92] (DUS characteristics). The elaboration of these conditions will be done in the next chapter.

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[90] BARTON, John H., 2004. Acquiring Protection for Improved Germplasm and Inbred Lines. *In:* ERBISCH, Frederick H., ed. *Intellectual Property Rights in Agricultural Biotechnology.* Cambridge: CABI Publishing. p. 25.

[91] LLEWELYN, Margaret, and COOK, Trevor, 1998. *Plant Variety Rights: An Outmoded Impediment. A Seminar by the Intellectual Property Institute, 19 February, 1998*. London : The Intellectual Property Institute.

[92] Article 5(1) UPOV 1991, Section 4 (2) UK Plant Varieties Right 1997, Section 14(1) Malaysian Protection Of New Plant Varieties Act 2004.

Another term which is also relevant in the context of PVR is 'farmers' rights.' The term 'farmer' is legally defined as any person who -

(a) cultivates crops by cultivating the land himself;

(b) cultivates crops by directly supervising the cultivation of land through any other person; or

(c) conserves and preserves, severally or jointly, with any person any traditional variety of crops or adds value to the traditional variety through the selection and identification of their useful properties.[93] The issue of farmers' rights arises in a quest to counterbalance the stronger property rights recognized for formal breeders of commercial plant varieties.[94] The concept of farmers' rights was formally introduced by the Food and Agricultural Organization (FAO) commission through a special resolution annexed to the original FAO International Undertaking of 1983. The FAO Conference Resolution 5/89 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.'[95]

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[93] Section 2 Malaysian Protection Of New Plant Varieties Act 2004.

[94] PATEL, Kirit K., 2004. Farmers' Rights Over Plant Genetic Resources in the South: Challenges and Opportunities. *In:* ERBISCH, Frederick H., ed. *Intellectual Property Rights in Agricultural Biotechnology.* Cambridge: CABI Publishing. p. 96.

[95] *Ibid.,* ANDERSEN, Regine, 2006. Realising Farmers' Rights under the International Treaty on Plant Genetic Resources for Food and Agriculture, Summary of Findings from the Farmers' Rights Project (Phase 1). *FNI Report 11/2006*, Lysaker, Norway: The Fridtjof Nansen Institute. Available at:
<http://www.alphagalileo.org/nontextfiles/FR_core_findings.PDF> [Accessed 18 January 2008].

In relation to the PVR, the above description of farmers' rights are perceived as very general in nature, whereas a much more specific definition and interpretation would be necessary to ascertain the scope of the rights. As far as UPOV 1991 is concerned, the farmers' rights can indirectly be inferred from Article 15(2) by way of optional exception. It states that: ….

'….each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety…'

It follows from the above provision that the countries which have acceded to UPOV 1991 are given the option to recognize farmers' rights in relation to their customary practice in farming activities. These may include the right to access improved plant varieties and use farm-saved seed of commercial varieties for planting and exchange, the right to grow, improve and market local varieties and their products, the right to be compensated for the use of local varieties in the development of new commercial products by outsiders, as well as the right to participate in decision making processes related to acquisition, improvement and use of plant genetic resources for food and agriculture.[96]

In relation to PVR, farmers who play the role as breeders are also given the equal rights which are provided for breeders of plant varieties under the Malaysian Protection of New Plant Varieties Act 2004. Section 13(1) of the 2004 Act says that:

[96] PATEL, Kirit K., *supra,* Note 94.

‘An application for the registration of a new plant variety and grant of a breeder’s right under section 12 shall only be made by-

(a) a breeder;

(b) the employer of the breeder;

(c) the successor in title of the breeder;

(d) a farmer or group of farmers, local community or indigenous people who have carried out the functions of a breeder;

(e) any government or statutory body which has carried out the functions of a breeder.’

The issue of farm-saved seed by farmers is also part of discussion on plant breeders’ exemptions which are enunciated under Article 15(1) UPOV 1991. This exemption is a part of ‘farmers’ privilege’, a concept which is used *inter alia,* in the context of the exemption for farmers who used saved seed for a further round of producing the harvest.[97] The concern has been voiced out by many proponents of farmers’ rights as well as developing countries in view of the proliferation of monopoly of large companies which indirectly affect farmers’ choice in the market in particular and farmers’ rights in general.[98] As far as this thesis is concerned, the above issue would also be covered in the next chapter, when discussing the scope of breeders’ rights under UPOV 1961, 1971 and 1991.

To recapitulate,

- “PVR” or “PBR” refers to a bundle of exclusive rights as enunciated in UPOV, granted to the breeders of a new variety of plant.

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[97] MOUFANG, Ranier, *supra.* Note 21.
[98] *Ibid.,* p. 99.

- "Farmers' rights" signifies the customary rights arising from the practice of farmers, *inter alia*, to reuse and exchange seeds from their harvests.

(viii) *Sui generis* protection

'*Sui generis'* is a Latin phrase which literally means 'of its own kind; unique.'[99] The term is usually used to refer to the event, situation, action material, person, entity or any such things which are clearly ascertainable and are unique of its kind. The term *sui generis* appears in the provision of the TRIPS Agreement in relation to patentable subject matter under Article 27. Article 27(3)(b) states that:

'Members may exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof…'

Interestingly, there is no definite system or regime which is specifically obligated by TRIPS on member states in relation the phrase 'effective *sui generis* system'. Industrialized nations, in particular those who subscribe to UPOV are of the view that the phrase refers to the UPOV-based PVR system, on the fact that UPOV is a proven system of protection for plant variety. UPOV has also slowly and gradually gained membership from around the world.

[99] ANON., 2005. *The Oxford Dictionary of Philosophy.[*online] Oxford: Oxford University Press. Available at: <URL: http://www.answers.com/topic/sui-generis> [Accessed 20 January 2008]

It is also worth noting those countries which are not UPOV members have the option to replicate or incorporate the provisions of UPOV in their national laws without joining this international organization. In this way, they would retain the freedom to act in the country's interest and change the law as and when required.[100] The scope of Article 27(3)(b) TRIPS Agreement will be analyzed in the next chapter.

In short, for the purpose of this thesis, the term *'sui generis'* system or protection simply refers to the UPOV-based PVR system.

1.6 Conclusion & Contribution

This thesis contributes in highlighting the ways by which Malaysia as a developing country could improve and enhance its existing IP laws on agricultural biotechnological inventions. The findings and proposals which are substantially incorporated in Chapter 6 could be used as an academic reference, especially to those involving with IP laws in Malaysia. The thesis is also informative in the sense that it covers the discussion on recent developments in EU in general, the UK and the U.S. in relation to laws relating to plant biotechnology. The writing ultimately contributes towards global harmonization of IP laws, as Malaysia itself is committed to enhance its IP regime in order to become part of the global players in the future.

[100] NIJAR, Gurdial Singh, *Legal and practical perspectives on sui generis options*,[online] Available at: <URL: http://www.twnside.org.sg/title/gsn-cn.htm> [Accessed 20 January 2008]

Chapter 2

The International and European Legal Background

2.1 Background

Although IPRs fall under the domain of national law and hence vary from country to country, industrialized countries in particular have gradually been achieving an international harmonization of patent laws as well as their expansion in scope. In the 1880s, the first international treaty to regulate IPRs at the international level was adopted: the Paris Convention on the Protection of Industrial Property (hereinafter the Paris Convention). As this chapter focuses on the international intellectual property system, the international treaties which include the Paris Convention, the UPOV Convention and the TRIPS Agreement will be discussed in considerable detail. In addition, the role of WIPO as a specialized agency of the United Nations to promote the protection of intellectual property throughout the world will also be covered in this chapter.

The other part of Chapter 2 is devoted to examine the position of European patent laws, namely the European Patent Convention (EPC) and the EU Directive 98/44. Although Europe's position on patentability is still not very clear, this thesis seeks to analyze the relevant provisions of EPC 1973, 1978 and 2000, as well as the interesting development of law which can be seen in the EU Directive 98/44. The Directive signifies an attempt towards European harmonization in the area of patent laws.

Chapter 2 also focuses on the important international agreement in the area of IPRs namely TRIPS. The negotiation history, the issues and debates on Article

27 specifically and its current position will be looked into. Other than TRIPS, the Convention on Biological Diversity (CBD), Patent Cooperation Treaty (PCT) and Patent Law Treaty (PLT) will also be discussed briefly in this chapter, as they represent the effort of harmonization of laws at international level which is to some extent relevant to this thesis.

2.2 The Paris Convention on the Protection of Industrial Property

2.2.1 The origin and background

As mentioned in Chapter 1, the two legal rights with which this thesis is mainly concerned are patents and plant variety rights (PVR). The origin of both can be traced back in the Paris Convention, which created the Paris Union. The Paris Convention has played the role as the basic instrument for international patent protection. It provides minimal rules of protection, which were translated into the national patent legislation. The most significant part is the rule of national treatment,[101] by which foreign inventors shall be treated in the same way as their domestic counterparts and their inventions shall be granted the same level of protection. The need for such an international cooperation arose in response to the technology and commercial necessities which have taken place all over Europe and North America in the nineteenth century. In fact, the origins of intellectual property could be linked to the industrial revolution in Europe which serves as one of the key elements of the technological development.[102] The Paris Convention, concluded in 1883, was revised at Brussels in 1900, at Washington in 1911, at The Hague in 1925, at

[101] Art 2 of the Paris Convention
[102] TORREMANS, Paul, *supra,* Note 57 p.7.

London in 1934, at Lisbon in 1958 and at Stockholm in 1967, and it was amended in 1979.[103]

2.2.2 The relevant provisions

In relation to agriculture, it is interesting to note that it falls under the broad context of the term 'industrial property'. This is evidenced by Article 1(3) of the Convention which states that the term 'industrial property' shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.

The Paris Convention firmly established the principle that agricultural and plant products could be industrial property; however, this did not mean that such patents were not sought and obtained prior to the introduction of the Convention.[104] The language used within the Convention implies that it was already possible to protect plant products by one of the rights (including patents) covered by the Convention – what the Convention did was to firmly establish any such practice as a general principle.[105]

Other than Article 1(3), the substantive provisions of the Paris Convention relevant to this thesis are those which provide for national treatment, rights of priority and patent rules. For example, Article 2(1) of the Convention provides

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[103] *Summary of the Paris Convention for the Protection of Industrial Property (1883)* Available at: <URL:http://www.wipo.int/treaties/en/ip/paris/summary_paris.html> [Accessed 22 May 2008].

[104] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. p. 10. Interestingly, the authors of this book give certain evidence that patent over uses of plant material were being granted even before the introduction of the Paris Convention, for example British patents were granted in 1637 to Amye Everard als Ball for a tincture of saffron and roses.

[105] *Ibid*., p. 11.

that 'nationals of any country of the Union shall, as regard the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention.' In this regard, Article 3 further provides: 'Nationals of countries outside the Union who are domiciled or who have real and effective industrial or commercial establishments in the territory of one of the countries of the Union shall be treated in the same manner as nationals of the countries of the Union'. These provisions obligate the countries that are members of the Convention to grant nationals of any member country, as well as nationals of non-member states who are domiciled or have a real and effective industrial or commercial establishment in the member states, the same protection they grant to their own nationals. This feature of offering the same treatment to all within the jurisdiction irrespective of nationality by each signatory state is seen as the culmination of the first round of patent harmonization.

Another important provision is Article 4bis of the Convention, which spells out the territoriality feature of patents. It says that 'patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not'.[106] Hence, it is apparent that a patent is not protected internationally, but nationally. By virtue of this Convention, a patent claim is required to be filed in each member state where patent protection is sought, observing the right to priority. In this sense, the duration

[106] Refer paragraph (1) Article 4 bis of the Paris Convention.

and scope of protection of each patent is dependant on the domestic legislation of each member state.[107]

2.2.3 The implementation

With regard to the implementation of this Convention, it has been implemented in the states adhering to the Convention by means of national Patents Acts. One hundred and seventy three states now adhere to the Paris Convention.[108] The Paris Convention clearly manifests that there are different national patent laws across the globe without imposing an obligation on member states, in particular the developing or less developed countries to harmonize their patents laws in accordance to the standards of the domestic patents laws of industrialized countries.

2.2.4 The significance

Slowly further conventions and revisions extended the scope of cooperation and the numbers of countries involved in it, yet it would be inaccurate to see the Paris Convention as a harmonizer of substantive law; rather it is best seen as a way of facilitating procedural compatibility between the patent systems of signatory nations.[109] In this regard, the current global scenario is somehow different, in particular after the establishment of TRIPS, which has managed to impose certain standards of substantive IP laws on member countries.

2.3 The Role of the World Intellectual Property Organization (WIPO)

2.3.1 Background

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[107] *Ibid*., para (5).
[108] Figure is correct on 21 June 2010, refer <http://www.wipo.int/treaties/en/ShowResults.jsp?treaty_id=2>
[109] TORREMANS, Paul, *supra,* Note 57 p.42.

WIPO is a specialized agency of the United Nations. It is dedicated to developing a balanced and accessible international intellectual property (IP) system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest. WIPO was established by the WIPO Convention in 1967 with a mandate from its Member States to promote the protection of IP throughout the world through cooperation among states and in collaboration with other international organizations. Its headquarters are in Geneva, Switzerland. WIPO's predecessor is an international organization called the United International Bureaus for the Protection of Intellectual Property – best known by its French acronym, BIRPI. BIRPI in fact originates from the International Bureaus under the Paris Convention and the Berne Convention.[110]

WIPO plays a significant, diverse role at the international level; that ranges from providing a forum for Member States to negotiate international intellectual property treaties and standards, to assisting governments in using intellectual property as part of their development strategies; from providing education and skills training on all levels, to delivering commercial intellectual property services to the private sector.[111] Currently, WIPO has a total of 184 Member States.[112]

2.3.2 Administration of national treaties

In relation to international treaties, WIPO administers a group of treaties which set out internationally agreed rights and obligations, and common

[110] World Intellectual Property Organization: An Overview. [online]2007 ed., p.6, Available at: <URL: http://www.wipo.int /freepublications/en/general/1007/wipo_pub_1007.pdf> [Accessed 11 June 2008]
[111] *Ibid.,* p.3.
[112] Figure is correct on November 16, 2010. Refer < http://www.wipo.int/members/en/>

standards for protecting IP rights. States which ratify the treaties undertake to recognize these rights and to apply the standards within their own territories. WIPO actively encourages States to accede to these treaties and to enforce their provisions. Widespread accession and consistent enforcement help maintain a stable international environment, inspire confidence that IP rights will be respected around the world.[113]

(i) Patent Co-operation Treaty (PCT)

As far as international harmonization of patent law is concerned, the role of WIPO can be seen significantly in the form of the Washington Patent Co-operation Treaty 1970 (PCT). It provides a unified procedure for filing patent applications to protect inventions in each of its Contracting States.[114] This means that a single international patent application under the PCT has legal effect in all the countries bound by the Treaty. Historically, the PCT was signed in Washington in 1970. The Treaty entered into force in 1978 initially with 18 Contracting States. The first international applications were filed on June 1, 1978. The Treaty was subsequently amended in 1979, and modified in 1984 and 2001.[115]

With regard to the procedures under the rules of the scheme, the applicant first of all files a single application. The treatment of that application can be subdivided in an international and a national phase. In the international phase the starting point is the filing of the application under the PCT rules with the national patent office of a Member State or with the international Bureau at

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[113] *Supra* Note 103, p. 28.
[114] 184 Contracting States as at July 07, 2010, Available at: < http://www.wipo.int/members/en/>[Accessed 07 July 2020]
[115] Refer <URL:http://www.wipo.int/pct/en/treaty/about.htm >[Accessed 12 June 2008]

WIPO in Geneva. In the application the applicant designates the Member States which are of interest to him and in which he would like to obtain a patent. In a second stage of the international phase an international search is carried out by one of nine selected national patent offices. In a third step the International Bureau will publish the publication. In fact, this international publication is one of the main advantages of the PCT system, as it provides a single and complete source of information for any scientist, rather than the pre-existing multiple national patent registers.

In the light of the results of the international search, the applicant has to decide whether or not to request that the fourth step of the international phase be carried out, which involves an international preliminary examination of the application by one of the nine selected patent offices. It is important to note that this examination is preliminary and no patent is granted at the end of the international phase. It is up to the applicant to decide whether he still wishes to pursue the application and move on to the national phase. It is only at the end of the national phase that each country involved will accordingly to its own rules decide whether or not to grant a national patent.[116]

Under this scheme, PCT applicants receive valuable information about the potential patentability of their inventions and have more time than under the traditional patent system to decide in which of the PCT countries to continue pursuing patent protection. All in all, the PCT system consolidates and streamlines patenting procedures, postponing the significant internationalization costs and providing applicants with a sound basis for

[116] TORREMANS, Paul, *supra,* Note 57 pp. 42-43.

important decision-making.[117] It worth noting at this juncture, the PCT system is still nowhere near to the establishment of a global patent system. This is attributed to the fact that not all countries participate in the system and most importantly, there is no harmonization of substantive patent law. What the PCT system provides is only a streamlined application procedure. In this regard, another relevant issue to be considered is whether worldwide patent law is ever likely to be feasible, taking into account the different levels of development, innovatory capacity[118] and legal systems around the world.[119]

The idea of having a 'world' patent system remains an important issue, despite the debates and arguments on the possibility of having one patent system for the whole world. Such an idea of the 'world' patent system is depicted in the form of one bureau or organization issuing 'world patents' which are automatically valid in all countries, replacing the current situation where each country has its own laws, own patent office and own courts. Interestingly, around the turn of this century, WIPO has started putting the pieces into places. Three primary building blocks have been identified by WIPO for a new world patent system namely a uniform set of procedures, a single international search tool and a uniform substantive patent law.[120]

(ii) Patent Law Treaty (PLT)

A uniform set of procedures is the first component which was actually put into place in June 2000, when the WIPO member states adopted the Patent Law Treaty (PLT). This treaty harmonizes the formalities that patent offices

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[117] *Supra,* Note 103, p. 35.

[118] For example, in 2006, the top countries of origin for PCT applications were again the U.S., Japan and Germany, *Supra,* Note 103, p. 36.

[119] TORREMANS, Paul, *supra,* Note 57 p. 43.

[120] GRAIN, 2002. *WIPO Moves Toward "World" Patent System.*[online] p. 1, Available at < http://www.grain.org/docs/wipo-patent-2002-en.pdf >[Accessed 13 June 2008]

undertake to administer patent applications. It defines one set of rules on how to prepare, file and manage patents in all the countries that sign on. Hence it streamlines formal procedures in respect of national and regional patent applications and patents, and thus making such procedures more user-friendly. PLT is open to States which are members of WIPO and/or States parties to the Paris Convention. It is also open to certain intergovernmental organizations.[121] Instruments of ratification or accession must be deposited with the Director General of WIPO. The PLT entered into force on April 28, 2005.[122]

Specifically, PLT signatories have agreed to a single internationally standardized set of formal requirements for national and regional offices, standardized forms to be accepted by all offices, filing date requirements, and procedures to avoid a loss of the filing date because of a failure to comply with formalities, simplified procedures before the patent office, basic principles for the implementation of electronic filing, and mechanisms to avoid unintentional loss of rights as a result of failure to comply with time limits. In essence, the Treaty does not attempt to harmonize substantive patent laws. Instead, the approach is more to the administrative side of the patent process.

Once the PLT was adopted in 2000, The WIPO member states agreed to move on to harmonization of the basic rules of patenting. This will be achieved through the Substantive Patent Law Treaty (SPLT). Hence, discussions on a draft Substantive Patent Law Treaty (SPLT) started in May 2001 and focused

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[121] As of June 13 2010, the PLT had 25 Contracting states, while 59 States and the European Patent Organization have signed the treaty, Refer < http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=4> [Accessed 07 July 2010]
[122] WIPO, 2000. *Summary of the Patent Law Treaty*. [online] Available at <http://www.wipo.int/treaties/en/ip/plt/summary_plt.html>[Accessed 13 June 2008]

on issues of direct relevance to the grant of patents, in particular: the definition of prior art, novelty, inventive step/non-obviousness, industrial applicability/utility, the drafting and interpretation of claims and the requirement of sufficient disclosure of an invention.[123] The WIPO Secretariat and Member States (known as the Standing Committee on the law of patents or 'SCP') agreed that other issues related to substantive patent law harmonization, such as first-to-file versus first-to-invent systems, 18 month publication of applications and a post-grant opposition system, would be considered at a later stage.

During the subsequent SCP meetings, proposals from a number of delegations led to the progressive broadening of the contents of the draft. While delegates agreed in principle on a number of issues, agreement on other topics proved more difficult. In 2006, Member States agreed that the time was not ripe to agree on a workplan for the SCP, and so put the SPLT discussions on hold. Delegations were divided broadly into those pressing to fast-track a limited number of technical issues, and those advocating a broader approach including a larger number of issues. Directed by its Member States, WIPO is now exploring potential areas of common interest.[124]

2.3.3 Recent development

The above development is an indication that the road to a uniform world patent system is fraught with dangers and unknown. Indeed the proposed setting up of a world patent system would have huge implications. It would mean the end of patent policy as a tool for national development strategies.

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[123] *Supra* Note 103, p. 29.
[124] *Ibid.*

As far as SPLT is concerned, its negotiation is largely a debate between the U.S. and Europe. The first draft of the treaty singularly reflected the U.S. patent law and the U.S. has made it clear that it is willing to go far as it can to secure the adoption of this new law. The Americans' main negotiable is the first-to-invent principle, and the related matter of a grace period. Their big non-negotiables appear to be business methods and biotechnology. Meanwhile Europe is defending the *status quo* of TRIPS, with Japan following its line. The developing countries are hardly part of the discussion at all, with a few exceptions led by Brazil.[125] Clearly, conflict of interest not only exists along North-South lines, but also amongst the industrialized countries themselves. Not surprisingly, the SPLT has been the most difficult piece of puzzle for WIPO.[126]

As discussed above, although a number of treaties, beginning as far back as the Paris Convention in 1883, have created a regime of mutual recognition between national patent systems, there has been very little substantive harmonization at a global level. To-date, the fact remains that TRIPS was the first international treaty to prescribe minimum standards for central issues like the subject matter of patent, the term of protection, and the mechanisms of enforcement.

2.4 The International Convention for the Protection of New Plant Varieties (UPOV)

2.4.1 Background

[125] *Supra* Note 115, p. 4.
[126] GRAIN, 2003. *One global patent system? WIPO's Substantive Patent Law Treaty*.[online] Available at
< http://www.grain.org/briefings/?id=159>[Accessed 17 June 2008]

UPOV was introduced with the main objective of protecting important results of agricultural plant breeding which are in the form of crop varieties. Since its adoption in 1961 in Paris, it has been one of the most significant intergovernmental organizations to provide protection for plant-related invention, in particular the new varieties of plant.

Historically, the idea of UPOV could be traced back to discussions in the 1950s. These discussions placed the emphasis on protecting the result of agricultural plant breeding in view of the opinion that this work should not be treated as industrial property protectable by the type of right envisaged by the Paris Convention. Interestingly, this view was based on the belief that, whilst the Paris Convention established the principle that plant products (in the guise of grain, flowers and flour) could be industrial property, the application of the principle did not, and should not, extend to the plants which produced these products. The reasons behind this view related to the capacity to meet the criteria for protection as well as the need to protect the public interest which vested in the production of new crop varieties.[127] Close readings of the academic writers and the courts' decision in Europe, for example in Belgium, Germany and the Netherlands show that between 1790 and 1970, several arguments were raised to deny plants patent protection. The largest category of objections focused on non-compliance with the legal requirements of patentability: invention conception, novelty, inventive step, industrial applicability and adequate disclosure. For example, a major objection to plant patents was that breeders' products lacked industrial applicability.[128]

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[127] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27, p. 136.
[128] This objection was at the core of a heated dispute surrounding the scope of the term 'industry' in Article 1 of the Belgian Patent Act. The similar objection was raised under Dutch legal doctrine in Article 3 of the 1910 Dutch Patent Act in respect of the definition of the term 'industry'. Refer

In 1950s, as far as the general scenario in Europe and UK is concerned, despite the fact that Paris Convention provides for a possibility of protecting plant products via patents, there was no political or legal will at that point of time to provide patent protection for plant varieties. Hence it was decided that a more appropriate response to demands of the plant breeders would be the introduction of a new form of right specifically designed to protect animate material. The result was the International Convention for the Protection of New Plant Varieties (UPOV). It is worth noting that central to the development of the UPOV Convention, was the involvement of the plant breeding organizations which had come into being during the 1930s and 1940s. The International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL),[129] which was founded in 1936, played a central role in promoting the need for such rights.[130] The most important contribution of the ASSINSEL in relation to UPOV is the 1957 ASSINSEL Conference in which twelve European countries participated; Austria, Belgium, Denmark, France, the Federal republic of Germany, Holland, Italy, Norway, Sweden, Switzerland and the UK. Clearly, the Conference is quintessentially a European affair.[131]

The conference delegates finally decided that, for reasons of perception and also because of the scant use made of patent protection where that possibility existed, it would be more appropriate to provide a specifically designed *sui generis* right. In particular, it was felt that plant material could not meet the

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VAN OVERWALLE, Geertrui, 1997. *The Legal Protection of Biotechnological Inventions In Europe and in the United States*, Belgium: Leuven University Press.

[129] ASSINSEL is now known as The International Seed Federation (ISF), after its merger with the International Seed Trade Federation (FIS) in 2002. Refer <http://www.worldseed.org/en-us/international_seed/history.html> [Accessed 24 June 2008]

[130] *Supra,* Note 27*,* p. 143.

[131] *Supra,* Note 27*,* p. 144.

patent law notion of novelty, and plant breeding programs could rarely be shown to be inventive. In addition, whilst the results of plant breeding were undoubtedly of industrial application, it would not be in the public interest to allow plant breeders to have an over-extensive monopoly and it would be difficult for plant material to meet the disclosure requirement.[132]

The 1957 Conference was followed by the second conference in November 1961, in which the 41 Articles of the Convention were adopted and the UPOV came into being. The Convention entered into force in 1968.[133] The UPOV Convention has been revised three times since 1961, with two substantive revisions taking place in 1978 and 1991. It is important to note that all three versions remain relevant for a discussion of European provisions. In particular, the 1978 and 1991 Acts remain relevant for they both form a reference point for determining an 'effective *sui generis* right' under Article 27(3)(b) of TRIPS, despite the fact that the 1978 Convention is now closed and any countries wishing to join UPOV can only do so under the Convention of 1991. At present, some states are parties to the 1978 Act while some are parties to the 1991 Act. Non-member states which wish to join the UPOV regime at present must join under the 1991 Act but there is no obligation for existing member states to ratify the latest version of the Convention if they do not wish to.

2.4.2 Purpose of adoption

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[132] *Ibid.*
[133] UPOV, 2007. *International Union for the Protection of New Varieties of Plants: What It Is, What It Does*.[online] Available at <http://www.upov.int/export/sites/upov/en/about/pdf/pub437.pdf> [Accessed 24 June 2008]

As far as the UPOV Convention is concerned, the main purpose of its adoption is to ensure that the members of the Union[134] acknowledge the achievements of breeders of new varieties of plants, by granting to them a property right on the basis of a set of clearly defined principles. By virtue of the UPOV, a minimum scope of protection is afforded to plant breeders as an incentive for the development of new varieties of plants, in order to provide sustainable progress in agriculture, horticulture and forestry. A legal protection is very essential as breeding new varieties of plants requires a substantial investment in terms of skill, labor, material, resources, money and time. The opportunity to obtain certain exclusive rights in respect of new varieties provides successful plant breeders with a better chance of recovering their costs and accumulating the funds necessary for further investment.[135] In this regard, it is worth noting that the ultimate rationale for the introduction of PVP is that it will promote food security because genetic engineering offers humankind an important chance to significantly increase yields in coming decades in view of the shortage of arable land to produce more food for an expanding population.

2.4.3 Criteria for a plant breeder's rights

For plant breeders' rights to be granted, the new variety must meet four criteria under the rules established by UPOV. Article 5 of UPOV 1991 provides that 'the breeder's right shall be granted where the variety is:

(i) new,

(ii) distinct,

(iii) uniform and

[134] 68 members as of October 22, 2009, Refer <http://www.upov.int/export/sites/upov/en/about/members/pdf/pub423.pdf> [Accessed 07 July 2010]

[135] *Supra,* Note 126.

(iv) stable.'

Obviously, the 1991 Convention requires that the varieties are new - new in the sense that they have not been previously commercialized or sold prior to the UPOV application being submitted (subject to the grace period outlined in Article 6(1b)). Besides, the new plant must be distinct from other available varieties and display homogeneity. The trait or traits unique to the new variety must also be stable so that the plant remains true to type after repeated cycles of propagation.[136] It is worth noting at this juncture that protection can be obtained for a new plant variety how ever it has been obtained, for example, through conventional breeding techniques or genetic engineering.

The scope of right is clearly spelt out in Article 14(1)(a) of the UPOV 1991 which says that: 'Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

(i) production or reproduction (multiplication),

(ii) conditioning for the purpose of propagation,

(iii) offering for sale,

(iv) selling or other marketing,

(v) exporting,

(vi) importing,

(vii) stocking for any of the purposes mentioned in (i) to (vi), above.'

2.4.4 Definition of 'plant variety'

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[136] Article 6-9 UPOV 1991.

Since UPOV is concerned with the plant variety rights, it is of paramount important to ascertain the definition of the term 'plant variety'. Article 2(2) of the 1961 UPOV Act clearly defined it as '…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 6.' Article 6 contained the substantive granting provisions: distinctness, uniformity and stability.

However, when the UPOV Convention was revised in 1978, the definition was deleted. The reason for this was the belief that there was sufficient consensus as to what was a variety to render the provision of variety superfluous. In the discussions leading up to the 1991 UPOV Act, it was proposed that a definition should be reintroduced. The reason for this was that a definition was seen as necessary in order to establish a clear concept between the rights available to a breeder for the genetic components of a variety which are potentially patentable, and rights which the breeder could claim over a grouping which collectively, and in a uniform and stable fashion, comprised the genetic components.[137]

In the 1991 Act, Article 1(iv) states that '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

[137] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27, pp. 160-161.

- considered as a unit with regard to its suitability for being propagated unchanged.

The above definition is apparently comprehensive and very well drafted and worded. Nevertheless, as mentioned previously in Chapter 1, the reintroduction of a definition into UPOV does not necessarily mean that there is now no ambiguity as to what is capable of being protected by a plant variety right and what is protectable by a patent. Instead, the reference in Article 1 of the 1991 Act to two types of plant variety, those which can meet the granting criteria and those which cannot, instills a degree of ambiguity into the Convention. For the purpose of plant variety protection, this ambiguity does not appear to be significant. However, the fact that the UPOV Convention specifically mentions two types of plant variety does bring into question the way in which the plant variety rights definition is used for the purpose of identifying what is excluded from European patent protection.[138]

2.4.5 Definition of 'breeder'

Other than the definition of the term 'variety', the 1991 Act also includes the definition of 'breeder'. It makes clear that a 'breeder' is not only a person who bred a variety, but also one who 'discovered and developed it'. Thus, discoveries are formally recognized as protectable under the Convention.[139]

2.4.6 The issue of 'dual protection'

Other than the ambiguity and vagueness surrounding the definition of the term 'plant variety', the issue of 'dual protection prohibition' is one of the

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[138] *Ibid.*, pp. 161-162.
[139] Under the text of the UPOV 1978 Act, it was possible to interpret that discovered varieties were protectable.

mostly debated and highlighted in the discussions on UPOV. PVR was at first conceived as an alternative to patent rights and it was accepted that the two kinds of IPRs should be kept separate. This so-called 'dual protection prohibition' refers to the prohibition of the grant of a patent over a plant variety, which was contained in Article 2(1) of both the 1961 and 1978 UPOV Acts. Article 2(1) of 1961 and 1978 UPOV Act says that: 'Each member State of the Union may 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 of protection under both these forms *may provide only one of them for one and the same botanical genus or species*.'(emphasis added)

Basically, this provision has been taken to mean that dual protection could not be sought using both ordinary patent law and a right under the UPOV Convention. This interpretation was given additional weight by the specific exclusion of plant varieties in the European Patent Convention. Hence, most of the criticisms for the plant variety right system in the 1980s revolved around the issue of this provision, and this has led to its removal from the text of the 1991 Act.[140] The elimination of this restriction was one of the major targets of those looking for a strengthened system of protection.

In spite of the removal of the said provision from the 1991 Act, there remain some countries within Europe which are still signatories to the 1961 and 1978 Acts, and have not brought their national provision into line with the 1991 Act as they opt to continue relying on the prohibition. Throughout all the

[140] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27, p. 147.

debates[141] leading to the 1991 Act, one theme is obvious – to make the plant variety right system more attractive to breeders. Hence the decision was to bring the rights closer to a patent-type right.

Ironically, some observers contend that the system remains less appealing to many developing countries. This observation could be attributed to the fact that many developing countries assert that the principles embodied in the UPOV Convention are not meant to serve their best interests, since the rights of farmers and indigenous communities may be compromised by its implementation. Besides, they argue that domestic research capacities in most of the developing countries are not internationally competitive, or where most farmers have been used to freely using and reproducing varieties elsewhere protected, introduction of IPRs that include UPOV system are not only prone to be met with substantial opposition by the rural communities, but are also unlikely to materialize into substantial pay-offs for either the informal breeding sector or the farming communities. That explains why some of the developing countries are well into drafting *sui generis* laws on protection of plant varieties which clearly move away from UPOV and towards the protection and implementation of farmers' rights, community rights and other provisions stemming from or related to the internationally binding Convention on Biological Diversity.[142]

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[141] The debates revolved around the changes in the UPOV 1991 which include the virtual elimination of both the farmers' privilege and breeders exemption. Member countries who sign the 1991 Act 'may' permit varieties for use on their own farms, but it will no longer be an automatic right. At the same time, breeders face new restrictions in the free use of genetic material, since the holder of a variety may now limit the right of another breeder to develop, produce, sell, stock or simply use any variety which is 'essentially derived' from a previously protected variety.

[142] Resistance to the UPOV 1991 is discussed in the later part of this Chapter (2.4.9.2). India and Nigeria have produced their own versions of *sui generis* PVP system as the alternatives to UPOV to ensure better protection for farmers and indigenous communities.

2.4.7 Limitation of rights

Another significant topic for discussions on the UPOV system is the two central derogations or limitations to the right. The function of these is to ensure that there is a proper balance between protecting the interests of the breeders and those of end users. The first limitation allows other breeders the right to use protected varieties in commercial breeding programs, while the second permits farmers to retain seed from one year to the next without having to pay an additional royalty. Both of these have undergone extensive revision in the most recent UPOV Act in order to take account of the changes to both the nature of plant breeding as well as the end use.[143]

(i) Research exemption

As far as the research or breeder's exemption is concerned, the UPOV system allows breeders to use protected material for research purposes even where there is a defined commercial objective to that research. This provision is contained in the compulsory exception in the Article 15(1) of the 1991 Act. It says that: 'The breeder's right shall not extend to

(i) acts done privately and for non-commercial purposes,

(ii) acts done for experimental purposes and

(iii) acts done for the purpose of breeding other varieties,…'

These exemptions are in fact a fundamental aspect of the UPOV system as it recognizes that real progress in breeding relies on access to the latest improvements and new variations. Access is needed to all breeding materials in the form of modern varieties to achieve the greatest progress and is only possible if protected varieties are available for breeding. In this regard, the

[143] *Ibid.,* p. 178.

breeder's exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to all the community of breeders.[144]

(ii) Insertion of the term 'essentially derived variety'

The right to use the protected variety for commercial breeding purposes is qualified by the need to show that the resulting variety does not fall within the 'essentially derived varieties' within the provision of Article 14(5) 1991 Act which states that the rights granted under Article 14(1)[145] shall also apply in relation to:

(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

(ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and

(iii) varieties whose production requires the repeated use of the protected variety.

Interestingly, the introduction of the term 'essentially derived varieties' in the UPOV Convention 1991 version was seen by many as one of the most important enhancements in relation to earlier versions of this Convention. This is because, under the 1978 Act, the breeder of any new variety is free to exploit that variety commercially irrespective of the genetic distance or proximity of the two varieties. In contrast, the 1991 Act curbs the freedom

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[144] Refer <http://www.wipo.int/sme/en/documents/upov_plant_variety.htm> [Accessed 01 July 2008]

[145] As mentioned earlier, this spells out the scope of the right which covers the production, conditioning, offering for sale, selling, exporting and importing, and stocking a protected variety for any of these purposes.

and states the right to commercialize may be exercised only if the variety concerned is not essentially derived.[146]

The provision on the essentially derived varieties was indeed intended to prevent the exploitation of mutations of protected varieties and varieties that had undergone a minor change in relation to the initial variety, for example by using biotechnology, without the holder of the initial variety right being able to share in the revenues.[147] Modern biotechnology means that a breeder can, for example, make single gene changes to a plant whilst in effect a clone with only a single gene differentiation and yet this is being presented as sufficiently different to the unaltered plant to warrant protection.[148]

With regard to the term 'essentially derived varieties', the definition set out in Article 14 (5) (b) UPOV Convention 1991 Act reads as follows:

'a variety shall be deemed to be essentially derived from another variety ('the initial variety') when

(i) 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,

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics

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[146] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. p. 181.

[147] KIEWIET, Bart, Essentially derived varieties, 2006. Available at: <http://www.cpvo.eu.int/documents/articles/EDV_presentation_PlantumNL_March_2006_BK.pdf> [Accessed 01 July 2008]

[148] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. p. 181.

that result from the genotype or combination of genotypes of the initial variety.'

It is clear from the above provisions that the characteristics that the derived variety must fulfill are cumulative. In other words, if one of the elements is not satisfied then essential derivation is not proved as required by the provision. The question of how far an essentially derived variety and the original variety have to resemble each other phenotypically is a difficult one to answer, since the definition offers scope for various interpretations. Establishing whether a variety is an essentially derived variety, based purely and simply on a genetic comparison, seems in any case not to be in line with the criteria set out in the definition of an essentially derived variety.[149] Hence, a number of different organizations and individuals have been involved in trying to define the parameters for determining if a variety is an essentially derived variety or not.

One of the useful interpretations is provided by International Seed Federation (ISF)[150]. ISF notes that even if there are not yet international agreed-upon professional rules and usages for assessing essential derivation and for solving disputes, the concept has already contributed to avoid infringement, and breeders being more careful in their breeding programs. According to the principle formulated by ISF, technically, for a variety to be considered as essentially derived, it must fulfill three requirements in relation to the initial variety while retaining the expression of the essential characteristics of the

[149] KIEWIET, Bart, *supra* Note 147.
[150] ISF, 2003. *ISF's View on Intellectual Property*.[online] Available at <http://www.worldseed.org/cms/medias/file/PositionPapers/OnIntellectualProperty/ISF_View_on_Intellectual_Property_(En).pdf. [Accessed 02 July 2008]

initial variety; clear distinctness in the sense of the UPOV Convention, conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety, predominant derivation from an initial variety. If one of these requirements is not fulfilled, there is no essential derivation.

From the legal aspect, the principle of dependence only exists in favour of a non-essentially derived protected variety. This means that the initial variety must be a protected one, dependence can only exist from one protected variety alone and an essentially derived variety can be directly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety. It is possible to have a "cascade" of derivation. However, each essentially derived variety shall only be dependent on one, the protected initial variety. A cascade of dependence shall not exist, the principle having been introduced to better protect the breeder of the initial variety and not those having made derivations from his work. This principle has mainly been introduced to protect more efficiently the initial breeder and not those who make derivations from his work.[151]

(iii) Farmer's privilege

Another feature which is seen as a limitation to the UPOV is relating to the practice of permitting farmers to retain seed from one harvest to the next for the purpose of resowing, which is also known as "farmers' privilege". From the start of agriculture, farmers have saved seed from their own crops for re-sowing the following year. In fact that practice was normal and is still essential in circumstances where the only seed available to plant a new crop is seed

[151] *Ibid.*

harvested from a prior season on-farm harvest. This practice was recognized in the earlier versions of UPOV that is the 1961 and 1978 Acts[152], wherein the owner or breeder had the right to control commercial propagation and marketing, but no other uses. This means that farmers were free to save seed for their own use for as long as they wished, and use the harvest without restriction.

Nevertheless, this 'privilege' as given to farmers had been clouded with suspicions by breeders within Europe and the U.S., that farmers were retaining larger than necessary amounts of the harvested material in order to sow greater area of land. This in effect denies the breeders a further return on their research investment.[153] Hence, with UPOV 1991, the breeders are given expanded rights which affect the farmers' privilege. Farm-saved seed is no longer automatically allowed, but only as an optional exception; a government may legalize seed saving for the farmer's own use – and even then the seed company has the right to a royalty payment. This is stated in Article 15(2) of UPOV 1991 by way of an optional exception, each member of the Union may, 'within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or other variety covered by Article 14(5)(a)(i) or (ii)".

[152] Article 5 of UPOV 1961 and 1978.
[153] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. pp. 190-191.

Reiterating the main purpose of plant variety protection which is to encourage the development of new varieties of plants, for the benefit of society, the Convention requires this optional exemption to be regulated 'within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, ...'. Should this exemption be introduced in a way that failed to provide an incentive for breeders to develop new varieties, then society would fail to benefit from the system.[154]

2.4.8 UPOV revision

With regard to the substantial revision to the UPOV Convention in 1991, it was done primarily for the reasons of strengthening the protection offered to the breeder in certain specific ways, as well as to reflect technological developments. More importantly, it also aims to clarify certain provisions in the light of the experience of UPOV Member States in operating the Convention since 1961.

2.4.8.1 Comparison of UPOV 1978 Act and UPOV 1991 Act

There are a number of important differences between the 1978 and the 1991 Acts of UPOV with regard to coverage, period, scope and exemptions.

(i) Number of protected varieties

One of the notable changes in the 1991 Act is the fact that 1978 Act covers plant varieties of nationally defined species or genera, whereas the 1991 Act covers plant varieties of all genera and species. This means that under the system of the 1978 Convention breeders can discover that their particular varieties cannot be protected in a country because the country does not

[154] *Supra,* Note 133.

provide protection for the species. The 1991 Convention addressed this problem by providing for the eventual protection in all UPOV member States of all plant genera and species. In terms of the protection period, the 1991 Act has extended it from a minimum of 15 years protection under the 1978 Act to a minimum 20 years.

(ii) Expansion of the exclusive rights

Another equally important highlight relates to the expansion of the acts subject to the breeder's authorization in respect of the propagating material of the protected variety. They do not only include production, offering for sale and marketing, but also reproduction (multiplication), conditioning for the purpose of propagation, exporting, importing and stocking for the just mentioned purposes. This new provision responds to the industry claims for a protection more similar to that conferred under the patent system.[155]

The other extension to the breeder's rights under the 1991 Act is the rights over the harvested material of the protected variety. The problem arises when a variety is taken to a country which does not provide protection for new plant varieties and used there to produce an end product, say cut flowers, which is exported back to a country where the breeder's variety is protected. In this situation, under the 1978 Convention, the breeder is unable to claim any remuneration from the exploitation of his variety. The extension in the 1991 Convention of the breeder's right to cover harvested material of a protected variety enables the breeder to claim remuneration in the situation.[156]

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[155] CORREA, Carlos M., 1992. Biological Resources and Intellectual Property Rights, *E.I.P.R.,* 5, p. 156.
[156] *Ibid.*

2.4.9 Expansion of UPOV

Whilst there may be some who question the value of the UPOV system even they would have to acknowledge that the Convention continues to have considerable influence, looking at the growing membership of UPOV as well as the fact that the number of rights granted has increased gradually. In fact, changes in IPRs in the field of plant varieties are necessary in developing countries not only to respond to external demands but also to protect local developments. Many developing countries have built extensive breeding capabilities, and both public and private entities are increasingly eager to ensure protection and reward for their research investment.[157]

2.4.9.1 UPOV Impact Study

In terms of the practical benefit which has been conferred via plant variety protection under the UPOV system, some very clear messages have emerged from the UPOV Report which was published in 2005.[158] The report, the first of its kind since the adoption the UPOV Convention in 1961, includes a study on the effects of plant variety protection in five countries, namely, Argentina, China, Kenya, Poland and the Republic of Korea. The report highlights the many and varied benefits of new plant varieties. Notable among these are the economic benefits, such as varieties with improved yields which lead to reductions in the price of end-products for consumers, and improved quality leading to higher value products with increased marketability.

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157 *Ibid.*

158 UPOV, 2005. *UPOV Report On The Impact Of Plant Variety Protection*. UPOV Publication No. 353(E) [Executive Summary is available online at < http://www.upov.int/en/about/pdf/353_Executive_Summary.pdf> [Accessed 22 July 2008]

It is interesting to note that the study indicates the range of ways in which plant variety protection can produce benefits and demonstrates that the benefits differ from country to country, reflecting their specific circumstances.[159] Individual country reports demonstrated increases in the overall numbers of varieties developed after the introduction of plant variety protection.[160] These included, for example, staple crops in the agricultural sector, such as barley, maize, rice, soybean, wheat; important horticultural crops, such as rose, Chinese cabbage, pear; traditional flowers, such as peony, magnolia, camellia in China; forest trees, such as poplar in China; and traditional crops, such as ginseng in the Republic of Korea. The reports brought out the importance of extending protection to all genera and species in a country in order to receive the full benefits of plant variety protection.[161]

The Impact Study also revealed that the introduction of the UPOV plant variety protection system and, in particular, membership of UPOV was accompanied by a large number of variety applications by foreign (non-resident) breeders, particularly in the ornamental sector. This was seen as enhancement of the global competitiveness for producers.

With regard to the domestic breeding, Argentina reported an increase in the number of domestic breeding entities, mostly in the private sector, for example, in soybean and wheat. The Republic of Korea showed an increase in the number of breeders of certain crops, such as rice and rose. Poland reported an increase in the number of commercial breeding entities and an

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[159] *Ibid.*, as commented by Kamil Idris, who was the UPOV Secretary-General, p. 3.
[160] The outcome of the report forms an important part of the thesis discussion of the need for an optimum form of protection.
[161] *Op.cit.,* pp. 88-89. Please also refer to UPOV, 2006. UPOV: The Impact of Plant Variety Protection. *WIPO Magazine*, Available at < http://www.wipo.int/wipo_magazine/en/2006/04/article_0004.html> [Accessed 22 July 2008]

overall increase in the number of improved varieties produced, despite a reduction in state-funded breeding and a decline in the overall number of domestic breeding entities. China reported on the stimulation of commercial breeding activities in domestic public research institutes and domestic seed companies, with an increase in the number of breeders (for example maize and wheat in Henan Province) linked to increased numbers of plant variety protection applications. The protected varieties generated income for breeders, including public research institutions and agricultural universities, and encouraged further investment in plant breeding. In short, the study has managed to show that an effective plant variety protection could encourage the development of new varieties of plants, and it aptly concludes that farmers, growers and breeders have access to the best varieties produced by breeders throughout UPOV member territories.

2.4.9.2 Resistance to the 1991 Act

Many developing nations, particularly those in Africa, have resisted ratifying the 1991 Act or adopting it as the standard for their plant variety protection laws. For example, the foreign ministers of the more than 50-member Organization for African Unity (now the African Union) issued a statement at a January 1999 meeting calling for a hold on IPR protection for plant varieties until an Africa-wide system has been developed that grants greater recognition to the cultivation practices of indigenous communities.

However, at a subsequent meeting of the Organisation Africaine *de la propriété Intellectuelle* (OAPIO), patent officials from sixteen francophone

African nations recommended that their countries adopt the 1991 Act.[162] Currently, Tunisia, Kenya and South Africa are the only African UPOV member states. Developing countries which are members of UPOV include Albania, Argentina, Azerbaijan, Belarus, Bolivia, Brazil, Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Dominican Republic, Ecuador, Georgia, Jordan, Kyrgyzstan, Latvia, Lithuania, Mexico, Morocco, Nicaragua, Panama, Paraguay, Poland, Romania, Tunisia, Turkey, Ukraine, Trinidad and Tobago Uruguay, Uzbekistan and Vietnam.[163] Nevertheless, the question whether or not UPOV negatively affects agriculture in developing countries is still much debated. The oft-cited argument is that UPOV's focus on patents for plant varieties hurts farmers, in that it does not allow them to use saved seed or that of protected varieties, and hence, it is not surprising that countries with strong farmers' rights, such as India, cannot comply to all aspects of UPOV.

All in all, the issue whether the evolved European model[164] is necessarily or automatically the best system for developing countries which includes Malaysia, in the 21st century, remains. Whatever the merits of plant intellectual property rights in Europe or other part of the globe, care has to be taken when using the European experience as a measure of how countries should respond to their TRIPS obligation.[165]

2.5 Trade-Related Aspects of Intellectual Property Rights (TRIPS)

[162] HELFER, Laurence R., 2004. *Intellectual Property Rights In Plant Varieties: International Legal Regimes And Policy Options For National Agreement*. Rome: FAO.

[163] There is a total of 68 countries which are members of UPOV as of January 15 2011. Refer :< http://www.upov.int/en/about/members/pdf/pub423.pdf>

[164] Other than the UPOV system, The EC Regulation on Community Plant Variety Rights of July 27, 1994 introduces a community plant variety right. This community plant variety right will not replace the existing national plant breeder's rights, but it will offer – albeit co-existing with national regimes – the opportunity to the breeder to get an exclusionary right valid throughout the Community, through submission of only one application.

[165] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. pp. 198-199.

2.5.1 Background

The Uruguay Round of multilateral trade negotiations held in the framework of the General Agreement on Tariffs and Trade (GATT) led to the Agreement Establishing the World Trade Organization (WTO Agreement).[166] For the first time those negotiations included discussions on aspects of IPRs which had an effect on international trade. The TRIPS Agreement was finally adopted at Marrakesh on April 15, 1994 as Annex 1C of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations. The Agreement came into force on January 1, 1995.[167] The TRIPS Agreement is perhaps the most far-reaching international instrument ever subscribed on IPRs. It covers all types of IPRs, with the sole exception to breeders' rights (only incidental referred to) and utility models.

The evolution of the TRIPS Agreement could be traced back to the growing realization particularly in the U.S., that the counterfeiting of trade marked products was having a considerable adverse impact upon trade revenue. The initiatives started as early as the late 1970s. The U.S. suggested that GATT jurisdiction was to be extended to trade mark counterfeiting. This proposition was argued by developing countries led by Brazil and India, on the ground that the intellectual property issues were the exclusive territory of WIPO. Eventually, after a series of negotiations and discussions, the TRIPS Agreement was realized[168], as an Annex to the WTO Agreement within the

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[166] The Uruguay Round negotiations concluded on December 15, 1993. The WTO Agreement was adopted on April 15, 1994, in Marrakesh.
[167] Official Journal EC, December 23 1994, L 336, Available at < http://europa.eu/scadplus/leg/en/lvb/r11010.htm> [Accessed 21 August 2008]
[168] The Preamble to the TRIPs Agreement commences with a statement of the desire of Members; 'to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade..'

Uruguay Round.[169] The fact that compliance with IP legislation would be linked to trade rights was undoubtedly one of the driving forces of the negotiation. Before TRIPS was concluded, many efforts failed to achieve what many governments, in particular the U.S. and Japan felt was becoming a necessity: a binding obligation to eliminate trade in counterfeit and pirated goods. There was resistance to the establishment of new norms. Some countries believed that no traditional standards were necessary or that they would impede legitimate trade. Others held the view that WIPO, not GATT, was the appropriate forum for treatment of these issues.[170]

The TRIPS Agreement establishes minimum universal standards of intellectual property protection that should be provided by all WTO member states.[171] It will supplement with additional obligations of the Paris, Berne, Rome and Washington[172] Conventions in their respective field.[173] Member states are free, however, to determine the appropriate method of implementing the provisions of the TRIPS Agreement within their own legal system and practice, and may implement more extensive protection than required.[174] The essential elements of standards concerning the availability, scope and use of patent rights are laid down in Articles 27-34 TRIPS Agreement. The provisions relating to eligible

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[169] BLAKENEY, Michael, 1997. *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement.* London : Sweet & Maxwell. pp. 1-6.
[170] GERVAIS, Daniel, 2003. *The TRIPS Agreement: Drafting History and Analysis*. London : Sweet & Maxwell. pp. 1-35.
[171] 153 members on 23 July 2008, Refer <
http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> [Accessed 16 November 2010]
[172] The Washington Treaty, adopted in 1989 under the auspices of WIPO, has not entered into force. Despite this, the TRIPS Agreement requires the compliance with the Treaty provisions, plus a number of additional rules. Refer: http://www.wipo.int/treaties/en/ip/washington/> [Accessed 03 September 2008]
[173] Refer Article 1(3) TRIPS Agreement.
[174] Article 1(1) provides that: '…Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement…'

subject matter, which are of special interest for this thesis, are laid down in Article 27 TRIPS Agreement.

2.5.2 Patentable subject matter under TRIPS

The general principle with regard to patentable subject matter in Article 27(1) TRIPS Agreement defines that patents shall be available for any invention, whether products of processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The Agreement stresses that patents shall be available, and patents rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.[175]

It is worth noting the patent section of the TRIPS Agreement was one of the most difficult to negotiate. It involved a number of key North-North as well as North-South issues. The negotiations on patentable subject matter in particular, represent a microcosm of the GATT treaty negotiations – confrontations and compromises between developed countries' desire to provide broad intellectual property protection and developing countries' concern for increasing inaccessibility of modern technology through overprotection.[176] The result is essentially impressive, in that the scope and coverage of the section are comprehensive, and makes TRIPS the most important multilateral instrument in this field. The TRIPS Agreement overcame the main weakness of the Paris Convention, and instead of relying on domestic law, TRIP defined the scope of a patent.[177] The TRIPS Agreement adds some

[175] Article 27(1) TRIPS Agreement.
[176] BAI, J.Benjamin, 1997. Protecting Plant Varieties under TRIPS and NAFTA: Should Utility Patents Be Available for Plants?, *Texas International Law Journal.,* 32, p. 141.
[177] GERVAIS, Daniel, *supra*, Note 170, p.220.

new standards to those already established by the Paris Convention, such as the prohibition of discriminatory treatment of patent rights as regards fields of technology (Article 27.1); the establishment of mandatory conditions for exclusions from patentability on *ordre* public and morality grounds (Article 27.2); the definition of 'minimum rights' (Article 28), and so forth.

In the field of life sciences, biotechnology and genetic engineering, Article 27(3)(b) TRIPS Agreement contains exclusionary provisions which are highly reminiscent of Article 53(b) EPC. It reads as follows; Article 27(3): Members may also exclude from patentability:

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreement Establishing the WTO.

The above provision indicates that the TRIPS Agreement provides for the exclusion of plants and animals from patent law, while plant varieties may be protected either by patents or by an effective *sui generis* system or by a combination thereof. In doing so, the TRIPS Agreement seems to take over the much disputed EPC distinction between plant or animal *per se* and plant or animal variety, leaving the first category without any legal protection.[178] Hence, the upshot is that plant and animals, including those that are

[178] OVERWALLE, Geertrui Van, 1997. *The Legal Protection of Biotechnological Inventions In Europe and in the United States*, Belgium: Leuven University Press., p.42.

genetically modified, may be excluded from patenting under Article 27(3)(b). This means that, unlike European law and other legislation that followed the same approach, this Article refers to 'plants and animals' and not to a certain classification thereof ('varieties', 'races' or 'species'). The distinction is important, as the prohibition to patent a 'variety' does not prevent in European countries the patenting of a plant as such. In the absence of any distinction, and in the light also of the second sentence of the same Article that introduces an exception for one particular classification ('plant varieties'), the exclusion is to be interpreted in broad terms inclusive of animal and plants as such, animal races and animal and plant species.[179]

Another element of the Article 27(3)(b) TRIPS Agreement is the exclusion of 'essentially biological processes' which is limited by the reference to processes 'other than non-biological and microbiological'. The concept of microbiological processes as an exception to the exception is present in the European legislation. Its aim in the TRIPS context is to limit the exclusion of patentability to traditional breeding methods, while preserving the possibility to obtain protection, for instance, on developments based on cell manipulation or, with the advances in biotechnology, the transfer of genes. According to TRIPS Agreement, processes employing microorganisms are patentable, in accordance with current practice in most countries.[180]

All in all, the wording of Article 27(3)(b) of the TRIPS Agreement apparently leaves the choice of protection system entirely to the members, which reflect on the one hand the broad range of existing systems, ranging from the US

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[179] CORREA, Carlos M., 1994. The GATT Agreement on Trade-related Aspects of Intellectual Property Rights: New Standards for Patent Protection, *E.I.P.R.,* 8, p. 328.
[180] *Ibid.*

where plant varieties may be protected by patents of by specific PVP rights or even by special plant patent, to the EU countries where PVP is confined to specific variety protection systems only. The possibility of excluding plant varieties from patent protection under TRIPS and the resistance from many developing countries to provide protection in this field resulted in the creation of *sui generis* protection according to their own concepts.[181]

2.5.3 *Sui generis* concept

A key issue with respect to a *sui generis* system for the protection of plants is determining what an effective system constitutes. It is interesting to note that the introduction of the *sui generis* concept in Article 27(3)(b) reflects two broad elements. First, a number of countries in the North and the South rejected the compulsory introduction of plant patents. Second, negotiators did not manage to agree on one specific alternative to patents. As a result, TRIPS gives member states a wide margin of appreciation in determining their obligation to introduce plant variety protection.[182] In other words, the *sui generis* option gives countries the option to develop a law that will not undermine the tradition of their farming communities and indigenous people in innovating and developing new plant varieties and enhancing biodiversity.

In the intellectual property context, a *sui generis* option is usually taken to refer to a specially coined IPR outside the traditional categories of IP protection. In this regard, UPOV has advanced its system as the principal workable example of a *sui generis* plant variety protection system. Hence, it is

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[181] For example, India seems to follow this path, via its Protection of Plant Varieties and Farmer's Rights Act 2001; Malaysia has its own pan-Malaysian version of PVP legislation via Protection of New Plant Varieties Act 2004.

[182]CULLET, Philippe, 2003. *Plant Variety Protection*.[online] Available at: <http://www.ielrc.org/content/f0304.htm> [Accessed 26 August 2008]

safe to assume that a UPOV 1991-compatible system would enjoy a presumption of the effectiveness required by this Article. Yet, the Article as it stands does not mandate UPOV protection and WTO members are thus free to develop another type of effective protection.[183]

In general, developing countries can make a choice amongst the following policy options, namely; first, to make provisions for the patent protection of plant varieties; second, to join the International Union for the Protection of new Varieties of Plants (UPOV) in either of both variants (UPOV 1978 or 1991); third, to provide for comparable plant variety protection (pvp) without formally joining the UPOV Convention; or fourth, to devise a *sui generis* system which is better designed to suit national interests and to take into account the protection demands of informal and local communities.[184]

In fact, the question of the introduction of plant variety protection is one that concerns mostly developing countries. Indeed, most developed countries had already introduced either plant patents or PVR before the adoption of TRIPS. Developing countries that are member of WTO were left with the choice of either adopting the existing regime proposed in UPOV or devising their own plant variety protection system adapted to their specific situation. In this regard, the prominence of the UPOV Convention in the debates concerning *sui generis* plant variety protection is in part linked to the fact that the interpretation of the concept of 'effective' *sui generis* system in Article 27(3)(b) TRIPS remains problematic.

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[183] GERVAIS, Daniel, *supra*, Note 170, p.225.
[184] SEILER, ACHIM, 1998, *Sui Generis* Systems: Obligations and options for developing countries, *Biotechnology and Development Monitor*, 34, p. 2-5.

The only generally agreed upon interpretation is that UPOV is an effective *sui generis* protection regime under TRIPS. This has led some countries such as the member states of the African Intellectual Property Organization for instance to simply adopt a regime modeled after UPOV-1991 and at the same time to commit themselves to join the UPOV Convention.[185] Nevertheless, space to manoeuvre still exists mainly because there is no formal reference made to the UPOV Convention. Furthermore, key elements for the shaping of effective *sui generis* systems are either unclear or not defined at all. While the TRIPS Agreement could have referenced the UPOV, and made its adoption a requirement, this was not done. At the time, one of the reasons for not referencing UPOV was specifically that the 1991 version had not been widely adopted.

From the perspective of developing countries, the term 'effective' means 'real' protection and not the strongest possible protection. Protection should be given not only to commercial breeders but, also, to traditional breeders. All that a *sui generis* law for plant varieties requires is an adherence to the minimum provisions of TRIPS, also consistent with obligations of countries under other international instruments to which they are parties, such as the CBD and its protocols. In fact, it is also suggested by some developed countries that what is 'effective' must be adjudged from the view-point of the rights-holder of the IPRs. But if traditional breeders are given rights under a *sui generis* law, then they too are rights-holders. Whether the law is effective in protecting their creativity must be assessed from the perspective of their interest as well. In these circumstances a *sui generis* law that balances the

[185] *Ibid.*

interest of both commercial breeders and traditional breeders can hardly be considered ineffective.[186]

2.5.4 Review of Article 27(3)(b) TRIPS Agreement

Another controversial issue with regard to Article 27(3)(b) TRIPS Agreement is the review of its provision. The provision, when it was introduced in 1994, provided for its own review within four years by the Council of TRIPS. In fact, Article 27(3)(b) is the single provision in the whole TRIPS Agreement subject to an early revision. This period is even shorter than the transitional period contemplated for developing countries.[187] This solution suggests how difficult a compromise on biotechnology-related issues has been and need for a deeper examination of the matter.[188]

Back to the review, in December 1998 the Council initiated preliminary work on the review of the provision of Article 27(3)(b) of the Agreement concerning inventions involving plants and animals, the review of which was due in 1999. By February 1999, Members in respect of which this Article was in force were invited to provide information on how the matter had been addressed in their country and how it was presently treated in their national laws. The Secretariat then contacted relevant organizations Food and Agricultural Organization (FAO), Convention on Biological Diversity (CBD) and the International Union for the Protection of New Varieties of Plants (UPOV) to request factual information on their activity in this field. It is worth noting at this juncture what the TRIPS Council has done is to require the developing countries to answer a three-page questionnaire. This information-gathering is to provide the basis for the review. The position of several leading developed

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[186] NIJAR, Gurdial Singh, *supra*, Note 100.
[187] Refer Article 65 TRIPS Agreement.
[188] CORREA, Carlos M., *supra,* Note 179, p. 329.

countries is that the review is merely to see how far countries are providing for the protection of plant varieties, namely, to monitor the implementation of the provision in relation to plant varieties. The EU and the U.S. state clearly that the review is thus limited and should not lead to a renegotiation of the Article. In particular they state that any attempt by developing countries to debate the relationship of TRIPS to other 'aspects such as competition, environment, and its impact on health and welfare ...must be resisted...'[189]

In fact, the discussions concerning the review of Art.27(3)(b) were amongst the most controversial discussion in the work of the Council for TRIPS. The discussions revealed differences between developed and developing countries and touched on major issues on which these two large groups of WTO Members may disagree, namely the patenting of life forms and plant varieties.[190] The discussions revolved around the perceived problems embedded in Article 27(3)(b), as highlighted by developing countries, *inter alia*; there are no parameters for what a *sui generis* system can amount to, no parameters for what is 'effective', the view that genes and microbiological processes are not inventions and therefore not patentable subject matter, a bias ingrained in TRIPS to protect breeders and biotechnologists at the expense of farmers and local communities, as well as the perceived conflict between TRIPS and the rights and obligations countries previously acquired under the CBD.[191]

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[189] NIJAR, Gurdial Singh, *supra*, Note 100.
[190] GERVAIS, Daniel, *supra*, Note 170, p.227.
[191] GRAIN, 2000. *For A Full Review of TRIPS 27(3)(b): An update on where developing countries stand with the push to patent life at WTO*. [online] Available at: <http://www.grain.org/briefing-files/tripsfeb00.pdf>; Summary of the debate is available at: <http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm>[Accessed 27 August 2008]

The review started, but it did not end. Developing countries made recommendations for clarification of TRIPS, but these were not acted upon. Finally, the deadline for implementation of Article 27.3(b) in developing countries, 1 January 2000, arrived before any conclusions could be drawn from the mandated re-examination of the text. In sum, although the review has not been a failure, it does not seem to have been very effective.[192]

The WTO's Fourth and Fifth Ministerial Conferences in Doha (9 – 14 November 2001)[193] and Cancun (10 – 14 September 2003) respectively, and the World Summit on Sustainable Development (WSSD) in Johannesburg (26 August – 5 September 2002) and the WTO's Sixth Ministerial Conference in Hong Kong in 2005 additionally failed to modify Article 27(3)(b) in any manner or form. The review of TRIPS Article 27.3(b) continues.[194] The current state of affairs is not unexpected as senior WTO officials privately confirm that whilst the review is supposed to cover the substance of the provision, rather than the way in which it has been implemented, they are convinced that the review will not be able to be concluded successfully until the stage where other provisions of the Agreement are also subject to review.[195] After all, the EU and the U.S. have made it loud and clear that the review is limited and should not lead to a renegotiation of the Article.[196] In short, as mentioned above, a positive outcome is not expected in the near future. The status quo may well be the most likely outcome, but it is interesting to note that both the African Group

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[192] *Ibid.*

[193] Paragraph 19 of the 2001 Doha Declaration has broadened the discussion. It says the TRIPS Council should also look at the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity, the protection of traditional knowledge and folklore.

[194] Refer <http://www.protimos.org/downloads/International%20Treaties/TRIPS/Review%20of%20Article%2027.3b%20of%20the%20TRIPS%20agreement.pdf> [Accessed 28 August 2008]

[195] TORREMANS, Paul, *supra,* Note 26, p. 398.

[196] NIJAR, Gurdial Singh, *supra*, Note 100.

which represents the developing countries, as well as the EU, see some scope and flexibility to discuss and possibly to protect issues such as traditional knowledge, protection of biodiversity and the promotion of farmers' rights.[197]

2.5.5 Important role of TRIPS

In conclusion, to parts of the business world, TRIPS has provided a means to help ensure that investments in research can reap financial rewards, in order that their products can be globally marketed under patented protection. In this regard, TRIPS means stronger intellectual property protection around the world which creates a new space on the global field within and around which the protection is further modified. With the partial exception of copyright and related rights, TRIPS represented a substantial institutionalization of protection at the level of international law. Nevertheless, from the view of most developing countries, while the TRIPS agreement serves as an important step in harmonizing international intellectual property systems, it currently fails to properly balance public and private interests, especially in the gap between rich and poor.

2.6 The co-existence of UPOV and TRIPS in protecting plant-related inventions

The preceding discussion in this chapter has deliberated on the two major international treaty systems that regulate issues on plant varieties and plant breeders' rights, namely UPOV and TRIPS. As has been highlighted, these two treaty systems each contain a comprehensive set of rules for their members regarding IPRs over plant varieties. As far as UPOV treaties are concerned, they adopt a *sui generis* system of protection especially tailored to the needs

[197] TORREMANS, *op.cit.,* pp. 400-401.

of plant breeders. The TRIPS Agreement on the other hand requires WTO Members to protect new plant varieties using patent rights, a *sui generis* system or some combination thereof.

As TRIPS provides member states with flexibility and because the treaty has an uncertain relationship to the UPOV conventions, national governments face a wide array of options in choosing the IP regime applicable to plant varieties. This section of the thesis seeks to indentify and analyze the issues that arise in relation to co-existence of these two major treaties.

Although the UPOV Acts have provided IPR protection for plant varieties for more than four decades, their significance has been somehow overshadowed by TRIPS, being the first and only IPR treaty that seeks to establish universal, minimum standards of protection across the major fields of IP, including patents. Although the TRIPS Agreement devotes only minimal attention to plant breeders' rights or PVP and does not even mention the UPOV Acts, its adoption has done more to encourage the legal protection of plant varieties than any other international agreement, comparing to the UPOV Acts which were initially drafted and created to address the needs of European plant breeders specifically.

Unlike all prior IP treaties, TRIPS is not a free-standing agreement concerned solely with IPRs. Rather, TRIPS is linked to a larger family of trade-related agreements, by which industrialized nations secured a commitment from developing nations to provide minimum standards of effective legal protection to intellectual property products, and in exchange developing nations received a commitment from industrialized countries to open their domestic markets to goods and other products manufactured in the developing world.[198] The result of this global bargain was widespread adherence to all WTO Agreements, including the TRIPs Agreement. As of July 2008, 153 states or customs territories were obligated to comply with TRIPs by virtue of their membership in the WTO.[199] As compared to UPOV, as at October 2009, only 68 countries are parties to the various UPOV Acts.[200]

Article 27.3(b) of the TRIPS Agreement contains the only textual provisions relating to PVP. Being a global instrument, it is interesting to note that TRIPS' provision on plant varieties do not incorporate any preexisting IP agreements, including the 1978 and 1991 UPOV Acts. This omission contrasts sharply with other fields of intellectual property, such as patents, copyrights and trademarks, for which TRIPs expressly requires WTO Members to comply with the standards of protection contained in preexisting IPR agreements, such as the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. As a result of this omission, WTO Members are neither required to become members of UPOV nor to enact national laws consistent with either UPOV Act in order to comply with their obligations under TRIPs. Although the drafting history of TRIPS does not explain this markedly different treatment of plant varieties, it seems likely that compliance with UPOV was not required because so few WTO Members were party to UPOV and those who were could not agree upon which of its two most recent Acts should serve as the standard for protection.[201]

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[198] HELFER, *supra* Note 162, p.34.
[199] Refer <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>
[200] Refer < http://www.upov.int/en/about/members/pdf/pub423.pdf>
[201] HELFER, *supra* Note 162, p.39.

In fact, Article 27.3(b) permits WTO Members to protect plant varieties using one of three distinct approaches: (1) patent law, (2) an effective *sui generis* system or (3) a combination of elements from both systems. Thus, unlike most other areas of intellectual property protected by TRIPs, Article 27.3(b) expressly grants Members significant discretion to choose the manner in which they will protect plant varieties and it contemplates that that discretion may be exercised differently by different states.

This discretion and the opportunity for divergent outcomes it engenders has significant consequences. On the one hand, TRIPS' failure to incorporate and build upon the preexisting UPOV Acts may have a deharmonizing effect, with states within the UPOV system enacting one type of plant variety protection law and states outside of that system enacting a different kind of law (which may or may not resemble each other). This could create significant complexities and uncertainties for plant breeders seeking to market protected varieties in different jurisdictions. On the other hand, this sanctioned diversity of legal approaches allows WTO Members to balance the protection of plant breeders' rights against the other important and competing societal goals.[202]

With regard to exceptions and limitations, as compared to limitations on plant breeders' rights permitted under the UPOV, the limitations on a patent owner's exclusive rights permitted under the TRIPS Agreement are far narrower. These limitations can be divided into exceptions to exclusive rights and compulsory licenses, which permit certain uses by third parties but require remuneration to the patent owner.

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[202] *Ibid.*

Back to the issue on *sui generis* protection for plant varieties under TRIPS, as noted above, TRIPS authorizes WTO Members to eschew patent protection for plants and plant varieties and adopt instead an 'effective *sui generis* system' of protection, without defining the term 'effective *sui generis'*. In this regard, there is a commentator who asserted that a state adopting national legislation in compliance with either the 1978 UPOV Act or the 1991 UPOV Act has satisfied its obligations under Article 27.3(b).[203] The argument and observation could be based on the practice of UPOV Member States which have successfully implemented UPOV provisions in their countries respectively.

However, from the perspective of developing countries which do not favour of joining UPOV, it can still be argued that the protection required by the two UPOV Acts is unnecessary for an 'effective *sui generis* system.' It is not necessary because article 27.3(b) neither requires plant variety protection laws to contain the same subject matter, eligibility requirements, exclusive rights, terms of protection or other detailed provisions of either of the two UPOV Acts., nor TRIPs requires WTO Members to structure their national IPR laws in ways that the two UPOV Acts do not.

The above argument is reinforced by the fact that TRIPs' drafters did not intend either UPOV Act to be the exclusive model for *sui generis* protection of plant varieties is confirmed by their failure to refer to the Acts anywhere in the Agreement. By contrast, where the drafters intended Members to comply with

[203] The commentator refers to Danielle Gervais; GERVAIS, D., 1998. *The TRIPS Agreement: Negotiating History and Analysis*. London: Sweet and Maxwell.

standards found in preexisting international IPR treaties, they stated so expressly.[204]

Nevertheless, it could be said that most provisions of the two UPOV Acts are fully consistent with an effective *sui generis* system, and countries who chose to join UOPV have adopted plant variety protection laws that are consistent with one or both UPOV Acts; 'effective' in the sense that the UPOV Member States have been benefiting from the system and the agricultural biotechnology industry in general has grown at a rapid stage. One of the evidences is based on the UPOV Impact Study, as discussed earlier.

Having said that, the issue of alternative PVP laws remains as an interesting agenda among developing countries. India for instance has designed its own '*sui generis'* system, namely the Protection of Plant Varieties and Farmer's Rights Act 2001. The Act provides a notable counterexample to the trend of following UPOV standards. That legislation seeks to implement both breeders' rights and farmers' rights by recognizing the concept of farmers' rights and by allowing farmers to register the varieties they cultivate. The Act also contains benefit sharing provisions that allow individuals and communities to claim compensation for their contributions to plant genetic diversity. At this juncture, it is noteworthy that Malaysia, being one of the developing countries, has enacted the Protection of New Plant Varieties Act 2004, which is pan-Malaysian in nature, and does incorporate provision on farmers' right.[205]

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[204] For example TRIPs, Article 2(1), which incorporates enumerated provisions of the Paris Convention for the Protection of Industrial Property.
[205] Malaysia is yet to accede to UPOV, as it needs to amend the 2004 Act to confirm to UPOV's standard and requirements.

Despite the above argument, it is submitted that UPOV is currently the only 'effective *sui generis'* model available in protecting plant varieties. Other '*sui generis*' models which have just been introduced and implemented by some countries like India and Malaysia for example, are relatively new and specifically tailored to respective countries' needs and uniqueness. Certain flexibilities should be allowed to suit the unique situation and local circumstances of each country that wish to accede to UPOV. It is true that historically PVR as introduced by UPOV was meant to provide incentives to commercial breeders, but being a dynamic system and to maintain the dynamism and relevancy to the seed and agriculture industry in the developing countries in particular, UPOV should be able to cater for the protection of all levels of breeders which include small farmers.

2.7 The European Patent Laws

The situation in Europe is slightly complicated in that there are two sources of European patent law. These two relevant and significant sources are the European Patent Convention (EPC) and the Biotechnology Directive (the Directive 98/44) on the legal protection of biotechnological inventions. For the purpose of this thesis, the brief history of EPC, its relevant provisions and interpretation by European Patent Office (EPO) will be discussed first, followed by the discussion on the provisions of the Directive 98/44.

2.7.1 European Patent Convention (EPC)

2.7.1.1 Background

All European countries have their own national patent law and most are also members of the EPC, the regional patent system which was established in 1973. The EPC is separate from the European Union (EU), and its membership is different; Switzerland, Liechtenstein, Turkey, Monaco, Iceland, Norway and Croatia are members of the EPO but are not members of the EU. The Convention is now (as of December 2010) in force in 38 countries.[206] The EPC is in fact a multilateral treaty providing an autonomous legal system according to which European patents[207] are granted. Hence, the EPC provides a legal framework for the granting of European patents, via a single, harmonized procedure before the European Patent Office (EPO). This means that under the EPC, a single patent application can cover all, or any selection, of the countries that have joined this Convention. The establishment of EPC is significant as it aims to reduce the administrative work required for obtaining patent protection in a number of its Member States, which would otherwise have to be applied for and prosecuted separately in each and every national jurisdiction in which the applicant wishes to protect its invention. It is worth noting EPC law takes precedence over national laws and these are required to be in harmony with it. In this regard, the EPO, which was established in 1974, has been playing a vital role as the principal representative of official patent opinion throughout Europe. Nevertheless, there is currently no single, centrally enforceable, European Union-wide patent.

Historically, the establishment of the EPC could be traced back to the problem of filing a separate patent application with different grant procedure in each country across the Europe when a patent applicant sought to obtain patent protection in Europe in a number of countries. While the EPC does not totally

[206] Refer <http://www.epo.org/about-us/epo/member-states.html> [Accessed 01 December 2010] In addition to the Contracting States, States may also conclude a co-operation agreement with the EPO, known as an extension agreement. The state then becomes 'extension state', which means European patents granted by the EPO may be extended to those countries by the payment of additional fees and completion of certain formalities.
[207] The term European patent is used to refer to patents granted under the European Patent Convention.

overcome the need for translations (since a translation may be required after grant to validate a patent in a given EPC Contracting State), it does centralize the prosecution in one language and defers the cost of translations until the time of grant.

The EPC 1973 was comprehensively revised at a Diplomatic Conference in November 2000. The new version of the Convention - abbreviated as 'EPC 2000' is now governing the European patent grant procedure and European patents. In fact, this was the first revision of the EPC since 1973 and aimed to modernize the European patent law to take account of developments in international law, to satisfy the needs of users, to eliminate unnecessary requirements and to introduce flexibility into the EPC. Besides, in the last 30 years, the patent landscape changed significantly and it became apparent that there was a real need to overhaul the dated legislation. The EPC 2000 entered into force on December 13, 2007.[208] Despite the comprehensive revision, the EPC 2000 leaves substantive patent law largely unchanged. The main amendments are in Article 54(3), concerning the novelty-destroying effect of prior European patent applications, and Article 54(5), expressly providing for use-limited product protection for a second or further medical use of a known substance.[209]

In relation to PCT, a European patent application may result from the filing of an international application under the PCT and the entry into 'European regional phase'. The European patent application is therefore said to be a

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[208] Refer <http://www.epo.org/patents/law/legal-texts/epc2000/faq.html> [Accessed 15 July 2008]
[209] *Ibid.*

‘Euro-PCT application’ and the EPO is said to act as a designated or elected Office.[210]

2.7.1.2 Important provisions of EPC

As far as EPC substantive patent law is concerned, Article 52 EPC, entitled ‘Patentable inventions’ is apparently one of the most important articles of the Convention. Article 52(1) states: ‘European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application’. This article constitutes the fundamental provision of the EPC which governs the patentability of inventions.

However, the EPC provides further indications on what is patentable, by introducing exceptions. Article 53 provides that: ‘European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such 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 shall not apply to microbiological processes or the products thereof;

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

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210 Refer <http://www.epo.org/patents/law/legal-texts/guidelines.html> [Accessed 15 July 2008]

For the purpose of this thesis, discussion is focused on Article 53(b) specifically, which is pertaining to the patents for plants and plant varieties. In essence, Article 53(b) imposes a restriction on the patentability of living matter. The provision has been repeated in the patent laws of all the signatory countries, for example, it appears in the UK Patents Act 1977 at Schedule A2 (section 76A) under item 3: 'The following are not patentable inventions -(f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.'

Historically, living matter had not been considered patentable under two distinct lines of thought: first, a legal view that biological material could not satisfy the criteria for patentability; and second, a strong ethical objection to granting a patent monopoly on any form of life. The exclusions of plant varieties from patentability is usually explained or defended on the ground that other forms of legal protection are available, namely, plant variety rights. Apparently, it might be thought that Article 53(b) would effectively exclude all patent applications for plant and animal varieties. Interestingly however, a line of cases in the EPO has laid down a very restrictive interpretation of Article 53(b), with the result that patents covering plants and animals can be obtained in many cases.[211] The relevant decided cases by EPO will be dealt with in a considerable detail in the latter part of this chapter.

Article 53(b) has attracted many views and criticism in terms of its interpretation. The provision has been clouded with uncertainties, in particular

[211] NOTT, Robin, *supra*, Note 11, p. 80.

the extent to which plants and animals can be patented. Since Article 53(b) provides an exception to patentability, it must be analyzed carefully. It is argued that being an exclusionary provision, it should be given a narrow interpretation.[212] The two exclusions in the Article 53(b) are; the exclusion of plant varieties and the exclusion of essentially biological processes for the production of plants.

Hence, there are basically three key issues which stem from the wording of the provision itself namely; first, the precise interpretation for the notion of plant variety, second, the meaning of the phrases 'essentially biological processes for the production of plants', and third, the interpretation or meaning of the second part of the provision 'this provision shall not apply to microbiological processes or the products thereof'. Each of these will be addressed in turn.

The term 'variety' is not defined in the EPC, although it is expressly defined in the UPOV. As far as patents for products are concerned, Article 53(b) excludes only plant varieties. Since the provision also refers to 'plants', it is clear that the legislature intended 'plant varieties' to mean something different from 'plants'.[213] This is in fact the view which has been adopted by the EPO Technical Board of Appeal in *Ciba-Geigy*. In its decision, the Technical Board of Appeal concluded that the 'very wording of Article 53(b) EPC before the semi-colon precludes the equation of plants and plant varieties which would also be at variance with the general sense of the provision. [214] The Board concluded

[212] CHRISTIE, Andrew, 1989. Patents for Plant Innovation. *E.I.P.R.,* 11, p. 395.
[213] *Ibid.*
[214] *Supra,* Note 22. In *Ciba Geigy*, the Board of Appeal adopted the definition of 'plant variety' found in the UPOV Convention.

that Article 53(b) prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety. In other words, the *Ciba-Geigy* decision confirms that Article 53(b) must be interpreted narrowly. This view was subsequently adopted and stated expressly by the EPO Board in *Lubrizol Genetics*.[215] Both *Ciba Geigy* and *Lubrizol* are important cases as they establish the principle that the exclusion from patentability under Article 53(b) was only applied to those plant varieties which were capable of being protected under the UPOV.

Nevertheless, the later cases such as *Plant Genetic Systems*[216] and *Novartis*[217] have changed the accepted view on patentability of transgenic plants. In the former, it was held that a transgenic plant embracing plant varieties within its subject-matter was not patentable. Wide claims, not specifically directed to plant varieties, but which would have included plant varieties within their scope and would have required the production of plant varieties to exemplify them, were refused. This was contrary to the previous practice of the EPO and its Boards of Appeal.

The *Novartis* case was widely regarded as a test case to determine the patentability of transgenic plants under the current EPO practice. Some of the key questions relating to the patentability of genetically modified plants were given a detailed consideration by the Technical Board of Appeal and were referred to the Enlarged Board of Appeal. In essence, the Enlarged Board of Appeal decided that Article 53(b) applies only to plant groupings which could be protected under plant variety rights. All other plant materials, including

[215] 1988, T320/87, at 8.
[216] *Supra,* Note 24.
[217] *Supra,* Note 25.

plant groupings, other than those protectable under plant variety rights, were patentable. Claims made to plant groupings which encompass plant varieties (such as plant species) were patentable provided that the claims were not specifically directed to an individual plant variety.[218]

Another issue to be considered is the extent to which a process for the production of a new plant is patentable. EPC Article 53(b) excludes from patentability 'essentially biological processes for the production of plants.' The phrase is rather unspecific, and this has triggered legal debates whether breeding methods which are only technical in a selection step but otherwise consist of biological steps are exempted form patentability as 'essentially biological'. It has been postulated that an essentially biological process could be defined, most simply, as one where natural methods are the dominant influence. Under such an interpretation, the criterion is the relative importance of natural versus human influences.[219]

The EPO guidelines for examination provide an interpretation to the term.[220] They state that: 'A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection....a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth, for example, a method of pruning a tree, would not be essentially biological since although a biological process is involved the essence of the invention is technical…'. Hence, the question whether a process is 'essentially biological' is one of degree depending on the extent to which there is technical intervention by

[218] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. p. 315.
[219] CHRISTIE, Andrew, *supra*, Note 212, p.398.
[220] Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 4.6.2.

man in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded.[221]

The second part of Article 53(b) EPC pertaining to the interpretation or meaning of 'microbiological processes or the products thereof' was one of the key questions considered by the Enlarged Board of Appeal in *Novartis*. The Board stated that the term 'microbiological' referred to those processes which involved the use of micro-organisms. Whilst plant cells are treated as micro-organisms for the purpose of the EPC, this does not mean that this treatment should be extended to include plants produced using a process involving micro-organisms. As the plant variety rights system does not distinguish between the manner of production for the purpose of deciding grant, therefore the patent system equally should not do so for the purpose of applying Article 53(b). With that, the Enlarged Board of Appeal effectively closed the door on using the second half of Article 53(b) to circumvent the exclusion of the first half.[222] Hence, based on this observation by the Board, to consider a plant genetic engineering process as microbiological would be quite far-fetched.

Following the decision in *Novartis*, as well as the amendment of the Implementing Rules, the current EPO practice is that, Article 53(b) applies only to plant groupings which can be protected under PVR. All other plant materials, including plant groupings, other than those protectable under PVR, are patentable. Claims made to plant groupings which encompass plant varieties (such as plant species) are patentable provided that the claims are

[221] CHRISTIE, Andrew, *supra*, Note 212, p.398.
[222] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. pp. 314-315.

not specifically directed to an individual plant variety. Irrespective of the manner of production, no claim may be directed to a plant variety as such, and the second sentence in Article 53(b) cannot be used to circumvent this.[223]

2.7.2 The Biotechnology Directive (the Directive 98/44)

2.7.2.1 Background

On 16 June 1998 the European Parliament and the Council of the EU passed the Directive No. 98/44/EC on the legal protection of biotechnological inventions. The Directive came into force on 30 July 1998, nearly ten years after the European Commission first proposed a draft directive to establish guidelines regarding biotechnological inventions. The Directive purports to harmonize the national laws of EU Member States relating to the protection of biotechnological inventions. The drafters of the Directive were aware that the biotechnological sector was, and still is, a rapidly developing sector, and that there was a need to establish a sound legal framework which would allow European businesses to develop and market products and processes arising from biotech inventions.

The objectives lying behind the Directive are outlined in its Recitals. The need for the Directive is spelt out in Recital 9, where it is stated that: 'Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty…' . In essence, the

[223] *Ibid.*

Directive recognizes the increasingly important role of the biotechnology and genetic engineering industry and the necessity of adequate legal protection for research and development in these areas, so that they may be profitable. In this respect, it also acknowledges the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which the European Community and its Member States are signatories. TRIPS specifically provides that patent protection must be guaranteed for products and processes in all areas of technology.

2.7.2.2 Relevant provisions

For the purpose of this thesis, some relevant Articles of the Directive will be examined. Besides, it will attempt to assess its implications for patent practice under the EPC. It should be emphasized at this point that the Directive is binding only on the EU Member States and does not necessarily have any direct effect on the EPC. Furthermore, it does not require the EU Member States to amend the EPC in accordance with its provisions, indeed it cannot do so since not all EPC Contracting States are members of the EU. The Directive is backed by the enforcement powers of the EU, which can coerce legislative action in Member States with the threat of sanctions. The power to coerce and enforce implementation of the objectives of the Directive contrasts with the relative lack of power of the EPC, which did not replace or supersede national laws. Having said that, the European Parliament and the Council of the EU have actually based many provisions of the Directive, in particular those relating to patentability, on the text of the EPC in view of its interpretation by the EPO and its various Boards of Appeal.[224]

The need for clarification of the issue of the exclusion from patentability of plant and animal varieties was one of the major driving forces behind the Directive. The issue is also interesting particularly in the light of the decision of the Enlarged Board of Appeal in *Novartis*, as it clearly illustrates that the Directive is likely to affect future interpretation and implementation of the EPC.[225] The Directive has two components: articles and recitals. The articles are directly binding on Member States, while recitals provide a context in which both Member States and the courts can interpret the articles. The provisions of the Directive with regard to the patentable and non-patentable inventions are set out in Articles 3 and Article 4. Article 3(1)[226] says that; 'For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.' In the context of the Directive, 'biological material' is defined in Article 2(1)(a) as 'any material containing genetic information which is capable of reproducing itself or being reproduced in a biological system'.

In Article 4, the Directive essentially restates the existing provisions of Article 53 of the EPC in respect of exceptions to patentability. However it does include some subtle differences and sets out to provide some clarification of the

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[224] BALDOCK, Claire and KINGSBURY, Oliver, 2000. The Biotechnology Directive And Its Relationship To The EPC*, Biotechnology Law Report,* Available at <http: http://www.boult.com/information/articleDetails.cfm?ArticleID=31> [Accessed 14 August 2008]
[225] *Ibid.*
[226] This corresponds to Para. 1 of Schedule A2 to UK Patents Act 1977.

meanings of these exclusions which have resulted in uncertainties in practice under the EPC. Article 4 reads:

‘1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

2. 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.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.’

Article 4(2) in effect allows the patenting of inventions concerning plants and animals if the technical feasibility of the inventions is not confined to a particular plant or animal variety. The Directive indicates that a plant variety is defined in accordance with the EC Regulation No 2100/94 on plant variety rights which states that a plant variety 'shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping can be:

- defined by the expression of the characteristics that result 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.' A plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants.[227] The definition therefore covers, for example, seeds as well as complete plants. The intended scope of the definition of 'plant variety' is further addressed in Recitals 30 and 31 of the Directive.

It is interesting to note the observation by the European Court of Justice (ECJ) when the Directive was challenged in the case of *Kingdom of the Netherlands v European Parliament and E.U. Council*[228]. The ECJ held, referring to Recitals 29-32 of the Directive, that a plant variety is defined by its whole genome.[229] Where a plant grouping is characterized by a specific gene, it is not precluded from patentability even if it comprises new varieties of plant.[230] In other words, modification of a single gene that creates a transgenic plant does not represent enough change to the entire genome to qualify as a new plant variety.[231] The effect of this decision is that, a transgenic plant of a plant grouping which contains modifications to its single gene is patentable, even though such transgenic plant embraces a new plant variety. However, if the modification could be proven or shown to affect the whole genome of plant grouping, which embraces and includes plant variety, then such plants ceases to be eligible for patent protection under the Directive, on the basis that a new

[227] Article 5(2) and (3) Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.

[228] Case C-377/98, ECJ.

[229] Recital 30 of the Directive reads: 'Whereas the concept 'plant variety` is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties.' Genome refers to all the genes contained in a single set of chromosomes, i.e. in a **haploid nucleus*. Each parent, through its reproductive cells, contributes its genome to its offspring. Refer JOHN, D., and ELIZABETH, M., ed., 2010. *Dictionary of Science*. 6th ed. Oxford: Oxford University Press. p. 354.

[230] *Ibid.,* paras 44 and 45 of the judgment. By way of definition, gene denotes a unit of heredity composed of DNA. It can exist in different forms called **alleles*, which determine which aspect of the characteristic is shown (e.g. tallness or shortness for the characteristic of height). Refer JOHN, D., and ELIZABETH, M., ed., 2010. *Dictionary of Science*. 6th ed. Oxford: Oxford University Press. p. 348.

[231] Recital 31 of the Directive reads: 'Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants.'

plant variety is not patentable. The whole point is that a plant variety is a very specific kind of plant grouping, and that other kinds of plant grouping should be eligible for patenting. The essence from the decision by the ECJ is that a new plant grouping which is characterized by a particular gene (and not its whole genome) is a generic innovation, not a plant variety, and cannot be protected under plant variety protection laws; whereas such an innovation may be deserving of protection and therefore should be eligible for patent protection and not excluded from patentability even if it comprises plant varieties.

Nevertheless, it seems that the wording of the Article 4(2) of the Directive does not clearly indicate whether it is intended that the phrase 'inventions which concern plants or animals' should extend to the plants and animals per se or whether it should be restricted only to processes for producing such plants and animals, thereby confining the patentee to unsatisfactory product by process protection for novel transgenic plants and animals produced by a novel process.

In relation to Article 4 of the Directive and Article 53(b) EPC, the EPO's practice is reflected in the decision of the Enlarged Board of Appeal in *Novartis*, wherein the Board indicated that genetically-modified plants were not to be treated as products of microbiological process. Hence, the exception to patentability on Article 53(b) applies to plant varieties irrespective of the way in which they are produced. At this juncture, it is worth noting that the Enlarged Board did make passing reference to the Directive, stating that its decision is in line with the provisions of Article 4. This definitive exclusion of plant and animal varieties from patent protection even where they are the products of a microbiological process is incorporated into the additions to the Implementing Regulations of the EPC[232] in order to bring it into line with the Directive.[233]

Obviously it remains open for courts in the individual countries signatory to the EPC to apply different standards; however, to date, national courts have not attempted to overturn the principles applied by the EPO, and certainly the English courts have adopted the same approach as the EPO. Having said that, it must also recognized that inevitably the English courts have not always followed the decisions of the EPO because they have taken a different view of the evidence or, more usually, have been provided with evidence which was not before the EPO.[234]

2.7.3 Some legal developments

In order to avoid any divergence of application or interpretation between the national granting offices and courts and the European Patent Office, on 6th June 1999, the Administrative Council of the EPO voted to amend its Implementing Rules to permit the EU directive to be used as a Supplementary Means of Interpretation.[235] It is clear from the amendment that the EPC is now to be read in light of the provisions of the EU directive. These came into force on the 1st September 1999. These provisions have to be followed unless it can be shown that they are inconsistent with the Convention. This means that

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[232] Rule 23c of the Implementing Regulations reads: 'Biotechnological inventions shall also be patentable if they concern: (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety; (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

[233] BALDOCK, Claire and KINGSBURY, Oliver, *supra*, Note 224.

[234] NOTT, Robin, *supra*, note 4, pp. 564-565.

[235] Rule 23b of the Implementing Regulations: '(1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.'

there is now greater cohesion between the policy and practice of the EU and the EPO.[236]

Essentially, effective and harmonized protection of biotechnology products is required for the internal market to function properly and for the biotech industry in Europe to fulfill its potential. From the point of view of industry, it would give greater certainty as to which inventions are likely to qualify for patent protection, and therefore which areas of research and development are most likely to yield sufficient return on investment.[237]

Whilst there has been extensive legislative activity providing a relatively coherent system of protection for all type of genetic material, the situation in Europe remains an uncertain one. Besides, whilst the framework for grant is in place, the issue of the proper scope of the rights will remain unclear until tested in the courts. To date there has only been limited litigation and until such time as the courts develop a coherent jurisprudence at the national and EU levels it is not possible to state with certainty and predictability as to exactly what is protectable and what maybe excluded from protection.[238]

2.8 Patentable Subject Matter: The EPO's Case Law

The way in which the regulations that cover agricultural biotechnology inventions (as set out in the EPC) are applied and interpreted is best exemplified by recent decisions that have been made by the European Patent Office (EPO) on individual patent cases. Since the EPC is somewhat ambiguous

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[236] LLWELEYN, Margaret, 2002. *Intellectual Property and Biotechnology: A European Perspective*, Available at <http://www.iprsonline.org/resources/biotechnology.htm> [Accessed 15 August 2008]

[237] As stressed in the European Union's White Paper, 'Growth, Competitiveness and Employment – The Challenges and Ways Forward into the 21st Century', COM (93) 700.

[238] LLWELEYN, Margaret, *supra*, Note 236.

as to the exact scope of the exclusion of plant varieties and essentially biological processes for the production of plants, one has to rely on the interpretation of the Technical Boards of Appeal and of the Opposition Divisions of the EPO in order to get some insight into the limits of the exclusion of plant varieties.[239] With the development of genetic engineering and the possibility of creating GM plants, the EPO found itself in untested waters with a lack of guidance from patent law. There has been considerable debate on the issue of what is protectable under patent and what is protectable under plant variety rights, and in the context of EPO's case law – most notably whether the exclusion under the first half of Article 53(b) EPC applies only to plant varieties protected under UPOV. At the EPO, a number of important decisions have been given in the field of plant genetics. For the purpose of this thesis, five cases decided by EPO and one case decided by the Supreme Court of Canada will be discussed in a considerable detail. These cases are selected because they are the landmark cases for the issues surrounding patentability of plant and plant varieties, and thus, to some extent serve as a useful guideline in determining the application and implementation of the patent laws in Europe.

(i) *Ciba-Geigy/Propagating Material (Case T-49/83)*[240]

The first consideration of the distinction between plants and plant varieties by the Technical Board of Appeal of the EPO occurred in 1984 in the *Ciba Geigy* decision. In fact, this is one of the earliest test cases to determine whether the exclusion under the first half of Article 53(b) EPC, applied only to plant varieties protected under UPOV. In this case, the claim related to 'propagating

[239] OVERWALLE, Geertrui Van, *supra*, Note 178, p.22.
[240] *Supra,* Note 22.

material, treated with chemical agents, for certain genera of plants.' The application referred to 'cultivated plants' bred from the coated propagating material without specific varieties being claimed individually. An objection was lodged on the ground that the claim fell within Article 53(b); however, the Technical Board of Appeal did not agree as no individual plant variety had been claimed and the opposition failed. The Board held that such a claim, without specific varieties being claimed individually, did not contravene the prohibition on the patenting of plant varieties in Article 53(b) EPC. In this regard, the Board said that plants and plant varieties cannot be treated as being the same thing for the purposes of applying Article 53(b). All that the Article excludes from protection are plant varieties. If the draftsmen had intended all plant materials to be excluded, then Article 53(b) would have been worded to have this effect.

It is also interesting to note that the Board in this case provided a definition of a plant variety[241] which to a large extent mirrors the principle which underpins the UPOV concept, namely a plant grouping which remains stable and uniform following repeated reproduction.[242] The legislator did not wish to afford patent protection under the EPC to plant varieties of this kind, whether in the form of propagating material or of the plant itself.

The Board points out that the very wording of Article 53(b) EPC before the semi-colon precludes the equation of plants and plant varieties, which would also be at variance with the general sense of the provision. Plant varieties

[241] 'The skilled person understands the term "plant varieties" to mean a multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle.'
[242] LLEWELYN, Margaret and ADCOCK, Mike, *supra* Note 27. pp. 294-295.

were excluded from European patent protection mainly because several of the signatory States to the EPC had developed special protection for plant breeding at national and international level. The Board maintained that the innovation in the claim did not lie within the sphere of plant breeding, which is concerned with the genetic modification of plants. Rather, it acted on the propagating material by means of chemical agents in order to make it resistant to agricultural chemicals. The new parameter for the propagating material, namely treatment with an oxime derivative, was not a criterion which can be characteristic of a plant variety as far as the protection of varieties is concerned. Therefore, there was no conflict between the protection of varieties or the patent as different forms of protection for propagating material treated in this way. It was not necessary for the object of the treatment always to be a plant variety, since the treatment could also be carried out on propagating material which did not meet the essential criteria of homogeneity or stability characteristic of a plant variety.[243] The subject-matter of the claims[244] was not an individual variety of plant distinguishable from any other variety, but the claims related to any cultivated plants in the form of their propagating material which had been chemically treated in a certain way. In this relation, Article 53(b) EPC prohibited only the patenting of plants or their propagating material in the genetically fixed form of the plant variety.

In short, in this case, the claims covered merely the application of a chemical treatment and not plant varieties as such. This is due to the fact that it wss not necessary for the object of the treatment always to be a plant variety, since the treatment could also be carried out on propagating material which

[243] *Supra,* Note 22.
[244] Claims 13 and 14 of the application.

did not meet the essential criteria of homogeneity or stability characteristic of a plant variety.

It is also worth noting the Board expressly affirmed the position of law that 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.[245]

(ii) *Lubrizol/Hybrid Plants (Case T-320/87)*[246]

The approach in *Ciba Geigy* was later applied by the Technical Board of Appeal in *Lubrizol/Hybrid Plants* case, where the Board held that 'the term plant varieties' means a multiplicity of plants which are largely the same in their characteristics (i.e. homogeneity) and remains the same within specific tolerances after every propagation or every propagation cycle, that is stability. The claims related to the processes for rapidly developing hybrids and commercially producing hybrid seeds in general, or belonging to the genus *Brassica*. The Board ruled that as the hybrid seed and plants from such seed were lacking stability in some traits of the whole generation population, they did not fall within the excluded category of plant varieties within the meaning of first part Article 53(b) EPC ('European patents shall not be granted in respect of plant or animal varieties..'). In other words, the hybrid plant at issue was outside the exclusion of Article 53(b) EPC as it was created by a multi-step process and it would not breed true in nature.

[245] *Supra,* Note 22.
[246] *Supra,* Note 23.

It is interesting to note that in analyzing the definition of 'plant variety', the Board acknowledged the fact that there was no definition of the term in the EPC. There was further no generally recognized taxonomic definition for 'variety' as there is for 'species' or 'genus'. In the case of the particular exception to patentability with regard to plant varieties, the legal history of Article 53(b) EPC made it clear that plant varieties were excluded from patent protection under the EPC mainly because several of the Signatory States had developed special legal protection for plant breeding at national and international level (the UPOV Convention) and such States were of the opinion that such special protection was better adapted to meet the interests of plant breeders.[247] In *Lubrizol*, the concept of 'plant varieties' in Article 53(b) EPC was analyzed by the Board in the light of the corresponding provisions in the UPOV Convention. It arrived at the conclusion that the term 'plant varieties' means a multiplicity of plants which are largely the same in their characteristics (i.e. 'homogeneity') and remain the same within specific tolerances after every propagation or every propagation cycle ('stability'). Thus, it was clear from the Board's analysis that possession of both characteristics of 'homogeneity' and 'stability' would be a prerequisite for a 'plant variety', within the meaning of Article 53(b) EPC specifically.

Another important issue which was highlighted in this case was whether or not a (non-microbiological) process wss to be considered as 'essentially biological' within the meaning of Article 53(b) EPC. The claims were initially refused by the Examining Division on the ground that the subject-matter of claims constituted essentially biological processes for the production of plants for which a patent should not be granted pursuant to Article 53(b) EPC. The Board

[247] *Supra*, Note 23, point 12 of reasons for the decision.

eventually ruled that it had 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.

In its decision, the Technical Board of Appeal stated that 'like any exception to a general rule of this kind the exclusion of 'essentially biological' processes for the production of plants (or animals) had to be narrowly construed. This is underscored by the fact that this exclusion does not apply to microbiological processes or the products thereof, as stated in Article 53(b) EPC. It was the opinion of the Board that the necessity for human intervention alone wss not yet a sufficient criterion for it not being 'essentially biological'. Human interference might only mean that the process was not a 'purely biological' process, without contributing anything beyond a trivial level. It was further not a matter simply of whether such intervention is of a quantitative or qualitative character.[248] After analyzing all the processes in the claims, the Board came to the conclusion that the claimed processes in *Lubrizol/Hybrid Plants* could not be considered as 'essentially biological' within the meaning of Article 53(b) EPC and thus were patentable.

Essentially, the above cases on the application of Article 53(b) addressed at length the meaning of the term 'plant variety'. It appears reasonable to conclude that the exclusion of plant varieties as stipulated in Article 53(b) EPC had to be interpreted narrowly, so as to give the widest possible benefit to the patentee. The decisions clarify that this provision was not meant to exclude plants *per se* from patentability but have to be seen in the context of the

[248] *Ibid*., point 6 of reasons of the decision.

UPOV Convention.[249] By virtue of *Lubrizol's* case, for a plant to be considered a plant variety, it must show capacity to survive on its own without human interference, thus it must be stable. If a plant is not stable it does not constitute a plant variety.[250]

Nevertheless, neither case involved a genetically engineered variety and in neither case did the invention or its embodiment directly produce a new plant variety. In short, both the *Ciba Geigy* and *Lubrizol* cases struggled to distinguish the exclusion of an innovation right based on phenotypic characteristics from the subject-matter of patentable genetic or chemical or breeding inventions.[251]

(iii) *Plant Genetic Systems (Case T-356/93)*[252]

In 1990, the EPO granted European Patent No. 0242236 to Plant Genetic Systems NV in respect of processes and products relating to the herbicide 'Basta'. The patents gave rights over genetically engineered plant cells, and, thereafter, over all subsequent seeds and plants derived from the engineered cells. The aim of patented invention in this case was to develop plants and seeds which were resistant to a particular class of herbicides, thereby enabling selective protection against weeds and fungal diseases. 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

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[249] JAENICHEN, Hans-Rainer and SCHRELL, Andreas, 1993. The European Patent Office's Recent Decisions on Patenting Plants. *E.I.P.R.,* 12, pp. 466-469, at p. 468.
[250] Note that this case was decided prior to Regulation 2100/94 (EC Council Regulation 2100/94 which established a system for Community plant variety rights (CPVR)), in which the DUS (Distinctness, Uniformity, Stability) criteria are explained. One might come to the conclusion that the reasons for the decisions influenced the European Community to legislate these criteria.
[251] FUNDER, Joshua V., 1999. Rethinking Patents for Plant Innovation. *E.I.P.R.,* 11, 551-574 at p. 557.
[252] *Supra,* Note 24.

to allow patents for plants defined in this generalized way, namely in non-variety-specific terms.[253]

In 1992 Greenpeace filed an opposition to the patent on the grounds that it violated both parts of Article 53 EPC. This was heard in 1993 by the Opposition Division, which upheld the patent. Greenpeace immediately lodged an appeal which was heard by the Technical Board of Appeal in 1994. The Board then reviewed the patent, analyzing separately the following three categories: (i) the plant cells and seeds, (ii) the process for producing the transgenic plant, and (iii) the transgenic plant. The appeal by the Greenpeace on Article 53(b) was based on the submissions which could be divided into two main parts, namely; first, that material claimed constituted a plant variety, and second, that some claims were for products resulting from essentially biological processes, not a microbiological processes, hence excluded from patentability.[254]

Under the first argument, Greenpeace asserted that the claims to plants and seeds would cover varieties formed from them, on the basis 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). The Technical Board of Appeal held that the claimed seeds and plants complied with the definition of plant variety since they were distinguishable, uniform and genetically stable.[255] Hence they were excluded from patentability.

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[253] CRESPI, R.S., *supra*, Note 10, p. 272.
[254] *Supra*, note 24.
[255] Point 40.4 of the reasons for the decision.

In reaching its decision, the 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 found that the claim embraced and encompassed 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 finally concluded that claims to genetically modified plant cells and to the process of producing genetically modified plants patentable, however claims to genetically modified plants themselves patentable. As the Board held in this case plant cells as such that culture much like bacteria and yeasts, do not fall under the definition of a plant or plant variety. In *Plant Genetic Systems*, the Board widened the term 'micro-organisms' to include not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, that is all generally unicellular organisms unseen to the naked eye, which can be propagated and manipulated in a laboratory, this including plasmids and viruses.[256] In this regard, it could be submitted that this is a huge benefit for the pharmaceutical industry in particular.

On the second argument by Greenpeace, the Board seemed to accept the argument and held 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 microbiological

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[256] See points 23 and 34 of the reasons for the decision, *supra*, Note 24; HEDLUND, Ebba and KALEN, Annika, 2006. *European harmonization regarding exclusions from patentability for plant and animal varieties* Available at : <URL : www.diva-portal.org/diva/getDocument?urn_nbn_se_oru_diva-483-2__fulltext.pdf > [Accessed 17 November 2008]

process when considered as a whole.[257] In the Board's judgment, the concept of ‘microbiological processes’ under Article 53(b), second half-sentence, EPC, referred to processes in which micro-organisms or their parts, were used to make or to modify products or in which new micro-organisms were developed for specific uses. Consequently, the concept of ‘the products thereof’ under Article 53(b), second half-sentence, EPC, encompassed products which were made or modified by micro- organisms as well as new micro-organisms as such. The Board further stated that as modern biotechnology often used or developed multi-step processes for producing plants which included at least one microbiological process step (for example, the transformation of cells with recombinant DNA), it wss critical to determine whether such processes as a whole could be considered to represent ‘microbiological processes’ within the meaning of Article 53(b), second half-sentence, EPC, and whether, owing to this, the products of such processes (for example, plants) may be regarded as being ‘the products thereof’ for the purposes of this provision.[258] In conclusion, the Board wss of the opinion that ‘technical processes including a microbiological step’ may not simply be equated with ‘microbiological processes’. Nor can the resulting final products of such technical processes (for example, plant varieties) be defined as ‘products of microbiological processes’ within the meaning of Article 53(b), second half- sentence, EPC. This part of the Board’s decision reflects the restrictive approach taken by the EPO in assessing the patentability of transgenic plants and the related processes to produce them.

[257] ‘The plant according to Claim 21 is thus not merely the result of said initial step, but also of the subsequent series of relevant agrotechnical and biological steps.’ –Point 40.5 of the judgment.
[258] Points 36-37 of the reasons for the decision.

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.

At this juncture, it is to be noted that the EPO policy made a 'U-turn' with the *Plant Genetic System* decision in relation to *Lubrizol*. Plants *per se* were no longer considered patentable, whereas plant cells were determined to be patentable.[259] It is equally interesting to note the effect of this decision 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, when the Technical Board upturned the hitherto prevailing interpretation of Article 53(b) EPC.[260] In other words, the decision seems to indicate a more restrictive approach being taken within the EPO. The decisions appeared to suggest that Article 53(b) EPC prohibited all claims 'embracing' plant or animal varieties. Hence, a claim which contains the possibility of encompassing excluded material will nonetheless be excluded. In one aspect, this restrictive approach can be read as a covert recognition of the role of

[259] However, the Board did not rule out protection for varieties *per se*. In a key part of its judgment (refer point 40.8 of the reasons for the decision), the Board said that if 'the subject matter of this claim the product of a microbiological process' then the exception to the exclusion would have operated and the claim would be valid by virtue of the second half or Article 53(b).
[260] CRESPI, R.S., *supra*, Note 10, pp. 272-274.

plant varieties play in protecting plant biotechnology following the revision of the UPOV Convention in 1991.[261]

It is also worth noting the decision in *Plant Genetic Systems* caused a great deal of concern not only among those wishing to see a clear pro-plant patenting policy within the EPO but also among those who wished to see clear blue water between that which is protectable under patent law and that under plant variety rights.[262] The concern which the case engendered was that it meant that, for the purpose of patent law, any single genetic change which was stable in its effect was considered to give rise to a variety. In addition, the distinction drawn by the Technical Board between essentially biological and microbiological was unclear and did not pinpoint when a process would be said to be no longer essentially biological.

Accordingly, in view of the outstanding importance of the legal issues addressed in *Plant Genetic Systems* case, in September 1995, the President of the EPO, under Article 112 EPC,[263] put the following question to the Enlarged Board of Appeals:

'Does a claim which relates to plants or animals but wherein specific plant or animal varieties are not individually claimed contravene the prohibition on patenting in Article 53(b) EPC, if it embraces plant or animal varieties?'

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[261] LLEWELYN, Margaret, *supra,* Note 236, p. 511.

[262] The decision by the Technical Board of Appeal has been criticized in legal literature. See, for exaomple, ROBERTS, Tim, 1996. Patenting Plants Around the World. *E.I.P.R.,* 18, pp. 534-535.

[263] Article 112 EPC: (1) In order to ensure uniform application of the law, or if an important point of law arises:
(a) the Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes. If the Board of Appeal rejects the request, it shall give the reasons in its final decision.

However, instead of actually dealing with the important matter concerned, the Enlarged Board rejected the above referral of the case on the basis that the *Plant Genetic Systems* case did not conflict with prior law which had not dealt with the patentability of a genetically modified plant.[264] This decision is disappointing to those who hoped that the Enlarged Board would be able to clarify the meaning of the exclusion of varieties from patentability.

In short, following this decision, claims directed to genetically engineered plants whose phenotype, that is, whose entirety of recognizable characters, has been made distinguishable in a stable and uniform manner by means of genetic manipulation, are probably not allowable. The Board regarded the claim directed to such plants as 'variety-comprising' and hence *prima facie* as not patentable. Since claims directed to plants which have been produced by genetic engineering methods will probably always comprise varieties, but the plants are only in the rarest of cases the result of a microbiological process, it could be assumed that plants produced by genetic engineering methods are not patentable under the jurisdiction of the Board.[265]

(iv) *Novartis/Transgenic Plant (Case G01/98)*[266]

In *Novartis*, the patent application at issue was related to transgenic plants and methods of preparing the same. The patent application with the title 'Anti-pathogenically effective compositions comprising lytic peptides and hydrolytic enzymes' was refused by the Examining Division. The product claims of the application claimed transgenic plants having specific foreign genes in their

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[264] EBA G03/95 (reason 4), OJ EPO 1996, 169.
[265] SCHRELL, Andreas, 1996. Are Plants (Still) Patentable? Plant Genetic Systems (EPO Decision T356/93). *E.I.P.R.,* 4, pp. 242-244.
[266] *Supra*, Note 25.

genome. Claim 19 as refused read as follows: 'A transgenic plant and the seed thereof comprising recombinant DNA sequences encoding: a) one or more lytic peptides, which is not lysozyme, in combination with; b) one or more chitinases; and/or c) one or more beta-1,3-glucanases in a synergistically effective amount.'[267] The expression of the foreign genes resulted in the production of anthipathogenically active substances which kill or inhibit the growth of disease-producing pathogens. The method claims of the application in Claim 23 claimed methods of preparing such plants, which essentially consisted of introducing genes into an ancestral plant by recombinant DNA sequence encoding. The claim read: 'A method of preparing a transgenic plant which is able to synthesis one or more lytic peptides together with one or more chitinases;….'[268]

The Examining Division refused the application on the basis that in the earlier case[269], the Board had held that a claim to genetically engineered plants and seeds, although not directed to any specific plant varieties, encompassed plant varieties which were not products of a microbiological process and, consequently, was not allowable under Article 53(b) EPC.

Novartis lodged an appeal[270] against this decision requesting that a patent be granted on the basis of the set of claims before the Examining Division. In particular it was argued that decision T 356/93 (*Plant Genetic Systems*) had inappropriately interpreted Article 53(b) EPC and should not be followed. The

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[267] *Ibid.,* Decisions of the Boards of Appeal T 1054/96 is available at <http://legal.european-patent-office.org/dg3/pdf/t961054ep1.pdf> [Accessed 08 October 2008]
[268] *Ibid.*
[269] T 356/93 (OJ EPO 1995, 545).
[270] This appeal case became T 1054/96. Once the appeal was pending, the Examining Divisions stopped the further handling of those cases in which Applicant insisted on prosecuting said type of claim (for plants and animals).

Board issued a summons to oral proceedings, which took place on 13 October 1997.

At the end of the oral proceedings, the Technical Board announced its decision to refer to the Enlarged Board of Appeal the following questions about how to interpret the plant variety exception in Article 53(b) EPC and about what must be taken into account in such an interpretation:

I. To what extent should the instances of the EPO examine an application in respect of whether the claims are allowable in view of the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or the products thereof, and how should a claim be interpreted for this purpose?

II. Does a claim which relates to plants but wherein specific plant varieties are not individually claimed ipso facto avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?

III. Should the provisions of Article 64(2) EPC be taken into account when considering what claims are allowable?

IV. Does a plant variety, in which each individual plant of that variety contains at least one specific gene introduced into an ancestral plant by recombinant gene technology, fall outside the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or the products thereof?

As a matter of fact, three of the above questions are related to the interpretation and application of Article 53(b) EPC and one of the four questions is related to Article 64(2) EPC.[271] For the purpose of this thesis, the decision and view of the Technical Board of Appeal in relation to the above four questions will be discussed first, before analyzing the decision given by the Enlarged Board of Appeal.

In answering the first question on the issue of the approach and method of examination to be adopted by the EPO to ascertain the patentability of claims of plant varieties, the Board considered both the substantive and literal approaches to the examination. The Board concluded that the substantive approach is the correct one to be applied when examining claim 19 for allowability in the light of Article 53(b) EPC. Thus, every potential embodiment of the subject-matter of claim 19 is either a plant variety or not. Insofar as it is a plant variety, it is not patentable. Insofar as it is not a plant variety, it is patentable. Higher taxonomic categories such as species, genus, family or order may be relevant as a convenient description of the field of application amongst existing plants of an invention, but for a particular embodiment the only relevant question is whether it is a plant variety or not. An embodiment cannot by itself be a species, genus, family or order.

The Board was not in favour of the literal approach as that would make examination for conformity with Article 53(b) EPC a very facile procedure. This is because if literal approach is the only way to examine the claim, all that is required of the patent office is to check that the words 'plant variety' (or the equivalent French and German terms) do not appear in any claims. If these

[271] Article 64(2) EPC : 'If the subject matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process'.

words do not appear, then Article 53(b) EPC is satisfied in relation to a claim to a plant. In this regard, the Board has difficulty in believing that the drafters of the EPC (and those of the Strasbourg Convention) would have included the provision of Article 53(b) EPC merely to prevent these words appearing in a claim, but without intending the provision to have any substantive function. The Board also stressed the responsibility of the EPO if it were to adopt the literal approach which would, in effect, be to abdicate any responsibility for examining the substance of the claim, and the outcome of an application would depend on the verbal skill of the patent attorney concerned.[272]

Another element of Question I as referred to the Enlarged Board of Appeal was the definition of the term ‘essentially biological process’ and whether Claim 23 fell under this definition. The Board was of the view that claim 23 was not allowable under Articles 84 and 53(b)EPC. The claim was not clear and concise as no identifiable method steps were recited. Rather all ways of obtaining the stated plant were claimed, including ‘essentially biological processes for producing plants’ which would fall under the prohibition of Article 53(b) EPC second part of first half sentence. The Board admitted the fact that to determine a correct approach in interpreting the term ‘ essentially biological process’ was problematic as a value judgment can be arrived at by different approaches. The phrase ‘essentially biological process’ ‘biological’ has been interpreted sometimes as contrasting with ‘technical’ and sometimes as contrasting with ‘chemical’ or ‘physical’. Given that the trend of developments was that biological processes were becoming better understood and in that sense possibly more technical, while gene technology makes use of natural mechanisms and in that sense is biological.

[272] *Supra*, Note 247.

The other element in Question I related to the meaning of the term microbiological process and the products thereof. The Board referred to the earlier case, *Plant Genetic Systems*, and concluded that genetically engineered varieties were covered by the prohibition of granting patents for plant varieties of Article 53(b) EPC even if they should in some sense be considered as the product of a microbiological process. The Board supported its view by citing the fact that it was more than ten years of scientific progress were necessary after the EPC was drafted before it became conceivable that varieties could be isolated with the help of techniques including microbiological steps. It, thus, could not have been the intention of the legislator to have plant varieties patentable as products of microbiological processes.[273]

With regard to the second question to the Enlarged Board of Appeal in relation to the 'more than a single variety' approach, the Board expressed some considerable problems which were posed by such an approach. On a plain reading of the language of Article 53(b) EPC which stated that patents shall not be granted for plant varieties in the plural, if one were to deduce from this wording of Article 53(b) EPC that a patent shall not be granted for a single plant variety but may be granted if its claims cover more than one variety, the Board was of the opinion that does not appear to comply with the normal rules of logic. Hence, avoidance of the prohibition of Article 53(b) EPC would then merely mean drafting a claim to a plant with some characteristics of any actual embodiment left unspecified. This would ensure that, at least theoretically, the claim covered potentially more than one variety.

[273] *Supra*, Note 247, points 30 and 40 of the reasons for the decision.

The third question to the Enlarged Board of Appeal pertainined to the application of the provisions of Article 64(2) EPC[274] to the effect that the protection conferred by the patent to a process patent will also extend to the products directly obtained by such process. The Board confirmed the practice of the EPO which is to ignore the provisions of Article 64(2) EPC when examining the allowability of process claims with respect to Articles 52 to 57 and 83 EPC, on the basis that such a provision addressed not to patent offices but only to courts in the Contracting States concerned with considering alleged infringements. Hence, the Board concluded that method claims for the manufacture of plants shall not be examined on their patentability in the light of Article 64(2) EPC. Therefore, applicants in the field of plant breeding by recombinant-DNA-technique have, in addition to all of the forms of available protection, protection for plants produced by the method as long as they are direct products of the method claimed.[275] At this juncture, by virtue of Board's view, it is therefore submitted that by obtaining a patent over a method of plant breeding, there is equally gained indirect patent protection over plant varieties.[276]

The final question as referred to the Enlarged Board of Appeal was on the issue of patentability of plant varieties which is produced by recombinant gene technology, which is the product of microbiological process. In response to the issue, the Board emphasized the fact the EPC is already suited to deal with genetic engineering as applied to plant varieties, apart from the provision of Article 53(b) EPC. In the Board's view, there appears no reason why the mere

[274] Article 64 (2) EPC says that: 'If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.'
[275] *Supra*, note 247, points 80 and 88 of the reasons for the decision.
[276] LLEWELYN, Margaret and ADCOCK, Mike, *supra,* Note 27, p. 309.

fact of being derived by genetic engineering should give the producers of such plant varieties a privileged position relative to breeders of plant varieties which meet all the requirements of Article 52(1) EPC[277] but have not been arrived at by genetic engineering.

The referral of the decision T 1054/96 was dealt with by the Enlarged Board of Appeal in G 1/98. It is particularly interesting to note that the Enlarged Board of Appeal indicated that it would favour the application because, in substance, it did not involve an application for plant variety. In effect, the decision overruled nearly all of the arguments presented by the Technical Board of Appeal.

In its answers, the Enlarged Board pointed out that the first question referred to it by the Technical Board was very broad and overlapped with the remaining questions. Therefore, it was preferable to deal with Questions 2 to 4 before dealing with Question 1. In summary, Questions 2 to 4 were then answered as the following conclusions:

Question 2: A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), even though it may embrace plant varieties.

Question 3: When a claim to a process for the production of a plant variety is examined, Article 64(2) EPC is not to be taken into consideration.

Question 4: The exception to patentability in Article 53(b), first half-sentence EPC applies to plant varieties irrespective of the way in which they were

[277] Article 52(1) EPC says that: 'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.'

produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are also excluded from patentability.[278]

In answering Question 2, the Enlarged Board seemed to disagree with the Technical Board's approach by emphasizing the fact that the subject-matter of a claim may not necessarily be equated with the scope of the claim. Yet the Enlarged Board admitted that it was not the wording but the substance of a claim which was decisive in assessing the subject-matter to which the claim was directed. In assessing the subject-matter of a claim, the underlying invention had to be identified. Thus, it was relevant how generic or specific the claimed invention was. The Enlarged Board further said that the applicant might claim his invention in the broadest possible form, that is the most general form for which all patentability requirements are fulfilled. At this juncture, the Enlarged Board expressed its disagreement with the Technical Board, as the former was of the opinion that in the event the applicant had made an invention of general applicability, a generic claim was not the consequence of the verbal skill of the attorney, but of the breadth of application of the invention.

The Enlarged Board also analyzed the definition of 'plant variety', and came to the conclusion that that the claimed invention neither expressly nor implicitly defined a single variety, whether according to the definition of 'plant variety' in Article 1(vi) of the UPOV Convention 1991, or according to any of the other definitions of 'plant variety'.[279] In this sense, it simply meant that it did not

[278] *Supra*, Note 25.
[279] The Enlarge Board also refers to the definitions in Article 5(2) of the EC Regulation on Community Plant Variety Rights as well as under Rule 23b(4) EPC, which entered into force on 1

define a multiplicity of varieties which necessarily consists of several individual varieties. In the absence of the identification of specific varieties in the product claims, the subject-matter of the claimed invention was neither limited nor even directed to a variety or varieties.[280]

The Enlarged Board went further to examine the historical legislative background which might contribute to an understanding of Article 53(b) EPC since the provisions on patentability closely followed the corresponding provisions in the Strasbourg Patent Convention (SPC). In fact, the Technical Board also took into consideration the intentions and considerations of the legislators when introducing Article 53(b) EPC. After a lengthy discussion on the historical background, the Enlarged Board eventually expresses its view that the purpose of Article 53(b) EPC corresponds to the purpose of Article 2(b) SPC[281] to the effect that European patents should not be granted for subject-matter for which the grant of patents was excluded under the ban on dual protection in the UPOV Convention 1961. Accordingly, inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the EPC provided they fulfilled the other requirements of patentability.[282] The reason that the drafting of the two Articles differed was that the EPC draftsmen were working within the constraints of the old UPOV ban on dual protection of plant varieties, which was abandoned in UPOV 1991, the desire to unify patent law throughout the EPC Contracting States and the varying availability of plant variety right protection in the various EPC

September1999, both are identical in substance to the definition Article 1(vi) of the UPOV Convention 1991.

[280] *Supra*, Note 25, point 3.1 of the reasons for the decision.

[281] Article 2(b) of the Strasbourg Patent Convention 1963 reads: The Contracting States shall not be bound to provide for the grant of patents in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to micro-biological processes and the products thereof.

[282] *Supra*, Note 25, points 3.6-3.7 of the reasons for the decision.

Contracting States. The Enlarged Board also makes an interesting observation of the legislators' intention to protect by the plant breeders' rights system biological developments for which the patent system was less suited and to keep technical inventions related to plants within the patent system based on the historical background.

In summary to the answer to Question 2, the Enlarged Board's decision was that, according to Article 53(b) EPC, a patent is 'in respect of plant varieties' and shall not be granted if the claimed subject-matter is directed to plant varieties. In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is not directed to a plant variety or varieties within the meaning of Article 53(b) EPC. The extent of the exclusion for patents is the obverse of the availability of plant variety rights. This is because the latter are only granted for specific plant varieties and not for technical teachings which can be implemented in an indefinite number of plant varieties.[283]

For Question 3, the Enlarged Board pointed out that the question appeared to have lost its relevance in the light of the answer to the preceding question, hence, if a plant variety may be covered by a product claim, there was little room for the argument that protection for the variety derived from a claimed process could be inconsistent therewith. In fact, Question 3 was answered in conformity with the established case law according to which the protection conferred by a process patent is extended to the products obtained directly by the process, even if the products are not patentable *per se*. The Enlarged Board confirmed that this practice takes account of the purpose of the

[283] *Ibid.,* point 3.10 of the reasons for the decision.

provision and is in accordance with its location in the EPC. The requirements on patentability to be examined by the EPO are contained in Part II, Chapter I EPC(Articles 52 to 57); Article 64(2) EPC belongs to Part II, Chapter III, containing provisions concerning the effects of patents and patent applications and is to be applied by the Courts responsible for deciding on infringement cases.

The Enlarged Board in turn addressed Question 4 in relation to the term 'microbiological process', that is whether the genetic modification of plant material might compromise a microbiological process within the meaning of Article 53(b), second half-sentence, EPC. According to the Enlarged Board, processes of genetic engineering, were not identical with microbiological processes. The term microbiological processes in the provision was used as synonymous with processes using micro-organisms. Micro-organisms are different from the parts of living beings used for the genetic modification of plants. On the other hand, it was true that cells and parts thereof were treated as micro-organisms under the current practice of the EPO.[284] This appeared justified since modern biotechnology developed from traditional microbiology and cells were comparable to unicellular organisms. This does not, however, mean that genetically-modified plants were to be treated as products of microbiological processes within the meaning of Article 53(b), second half-sentence EPC. Such an analogy and formal use of rules of interpretation would disregard the purpose of the exclusion in Article 53(b) EPC, that was to exclude from patentability subject-matter which is eligible for protection under the plant breeders' rights system.[285]

[284] T 356/93, (*Plant Genetic Systems*).
[285] *Supra*, Note 25, point 5.2-5.3 of the reasons for the decision.

In answering Question 4, the Enlarged Board of Appeal supported the view of the Technical Board of Appeal that the mere fact of being obtained by means of genetic engineering did not give the producers of such plant varieties a privileged position relative to breeders of plant varieties resulting from traditional breeding only. Therefore, it did not make any difference for the requirements under the UPOV Convention or under the Regulation on Plant Variety Rights, how a variety was obtained. This simply meant that the term 'plant variety' was appropriate for defining the borderline between patent protection and plant breeders' rights protection irrespective of the origin of the variety. The Enlarged Board also reasoned that refusing to allow genetically modified plants to be treated as products of microbiological processes would not preclude inventors from adequate intellectual property protection. This was due to the fact that a plant variety resulting from genetic engineering could qualify for protection under the UPOV Convention just as equally as those resulting from traditional breeding techniques.

At this juncture, it is important to highlight that the Enlarged Board made reference to Article 4(1)b and (3) of the Biotechnology Directive,[286] using language corresponding to Article 53(b) EPC, and concluded that the exclusion was intended to be interpreted in the sense outlined above, since Recital 32 of the Directive[287] postulated that a new plant variety bred as a result of genetically modifying a particular plant variety was still excluded from patent

[286] Article 4(1) of the EU Directive 98/44 reads: The following shall not be patentable: (b) essentially biological processes for the production of plants or animals. Article 4(3) reads: Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.
[287] Recital 32 of the EU Directive 98/44 reads: Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process.

protection, even if the genetic modification was the result of a biotechnological process.[288]

With regard to Question 1, the Enlarged Board pointed out that the problems raised in this question were dealt with in the answers to Questions 2 to 4. The only problem that was not addressed in these answers was how to decide whether a process can be defined as 'essentially biological'. However, the Board did not further address this problem, as the Applicant indicated that it was willing to amend the corresponding process claims to restrict the method claims to identifiable method steps in order to exclude essentially biological processes.[289]

In essence the decision separated the subject matter of the claim from the scope of the claim. An application for a patent of a transgenic plant may within the scope of the claim cover plant varieties, but this does not mean that the claim or the patent application should be rejected. Such a patent protection can be obtained for a transgenic or genetically modified plant under the EPC as long as the claimed invention can be performed with different plant varieties which conditions for patent (novelty, inventive step and industrial application) could be met. In addition, if an application is made for a process patent and a plant variety falls within the scope of the claim for a process, this does not mean that the process itself is not patentable. The *Novartis* case permits the patenting of plants provided a technical invention can be shown

[288] *Supra,* Note 25, point 5.3 of the reasons for the decision.
[289] *Ibid.,* point 6 of the reasons for the decision.

and plant varieties are not claimed specifically. In short, patents over plants are now permitted under the EPC.[290]

The Enlarged Board of Appeal decision in *Novartis* reflected a wider pro-patenting attitude in respect of protecting biotechnological inventions and has cleared some of the ambiguities in relation to the interpretation of the Article 53(b) EPC. The case also highlighted the relationship between the plant breeders' rights for plant varieties under the UPOV Convention and the 'plant varieties' exception to patentability under Article 53(b) EPC. In fact, *Novartis* has been regarded by many patent experts and commentators as one of the most significant plant patent cases affecting Europe in the sense that it has managed to elucidate the position and practice of EPO in patenting plant inventions other than plant varieties, as well as clarifying whether the exception to the exclusion applied to plant varieties produced by microbiological processes. Hence, as a consequence of the *Novartis* decision, it is now possible at the EPO to obtain broad claims directed to transgenic plants as long as they do not specifically relate to individualized varieties.[291] In other words, a plant variety, or a group of plants that could be defined as a variety, cannot form the subject matter of a patent application no matter how they are generated, but can be patent-protected if they are embodiments of inventions that independently qualify for patent protection.

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[290] ADCOCK, Mike, 2005. The Monsanto v Schmieser case: A European Perspective. *9th ICABR International Conference on Agricultural Biotechnology: Ten Years Later, Italy, 6-10 July, 2005*. pp. 1-10, Available at: < http://www.economia.uniroma2.it/conferenze/icabr2005/papers/Adcock_paper.pdf> [Accessed 26 November 2008]

[291] JAENICHEN, Hans-Raner, MCDONELL, L.A., and HALEY, J.F.Jr., 2002. *From Clones to Claims: The European Patent Office's Case Law on the Patentability of Biotechnology Inventions in Comparison to the United State Practice and Case Law.* 3rd ed. Cologne : Carl Heymanns Verlag KG. p. 18.

The decision is in line with the EU Directive,[292] in particular with Article 4(1) and (2), as well as the implementation of new Rule 23c(b) EPC, which was discussed earlier. Even though the EU Directive is not legally binding on the EPO Boards of Appeal, the *Novartis* decision is consistent with the Directive's provision as regard the patenting of plants. In fact, *Novartis* was the first case in which the EU Directive was used as a supplementary means of interpretation in helping to make the judgment. With the benefit of the ruling in the *Novartis* case and the EU Directive 98/44, the exception to patentability of plant varieties seems to only exclude a plant-related invention if the subject matter claimed is a product which is strictly limited to a specific plant variety or specific plant varieties. Ultimately however, the European patent remains a viable option for biotechnologist with plant-related inventions, even with the plant varieties exception of Article 53(b) EPC.[293]

(v) ***Plant Bioscience Limited (Case T83/05)***[294]

In 2002, the EPO granted a patent to a UK company, Plant Bioscience on a method for increasing a specific compound in *Brassica* species, that is Broccoli, through conventional (marker assisted) breeding methods. Specifically, the patent related to claims to a method for the production of *Brassica oleracea* (broccoli) with elevated levels of certain *glucosinolates*, wherein the method comprises several steps of crossing and selection using wild *Brassica oleracea* species and double haploid breeding lines, in addition to a step comprising the

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[292] Between the time that the Technical Board of Appeal in *Novartis* referred its questions to the Enlarged Board, and the Enlarged Board's decision in G 01/98, the European Commission adopted the Directive 98/44 on the legal protection of biotechnological inventions.

[293] MCCLATCHEY, Katrina, 2004. The Impact of Novartis On The European Patent Convention's Exception To Patentability For 'Plant Varieties'. *Okla.J.L.&Tech.,* 2. Available at: < http://www.okjolt.org/articles/2004okjoltrev21.cfm> [Accessed 14 October 2008]

[294] Available at: <http://legal.european-patent-office.org/dg3/pdf/t050083ex1.pdf> [Accessed 14 October 2008]

use of molecular markers to select hybrids with the desired genetic combination. In other words, the patent included the breeding methods, as well as the broccoli seeds and edible broccoli plants obtained through these breeding methods.

The Patentee argued that the exclusion should be interpreted narrowly, and that use of the molecular markers constituted a technical step over and above the production of the hybrid broccoli. The method was not just an 'essentially biological process' as it consisted of a step which was not a natural phenomenon. In addition, the patentee argued that the method was patentable as it required the use of a non-natural starting material, and because the wild strains required human intervention to being them into contact with the broccoli breeding lines.

The Appellants (who were the Opponents in the earlier Opposition Proceedings) argued that the use of the molecular markers insufficient to escape the exclusion provisions of Article 53(b). It was argued that Rule 23b(5)[295] does not contain an exhaustive definition of the excluded processes and that Article 53(b), which has a higher legislative rank than Rule 23b(5) according to Article 164(2) EPC, only excludes 'essentially biological processes'. This definition included the method of the above patent (*Plant Bioscience Limited*), even including the use of the molecular markers.

[295] Following the EU Directive 98/44, Rule 23b(5) EPC was brought into force in 1999 in an attempt to clarify Article 53(b): 'A process for the production of plants or animals is essentially biological if it consists *entirely* of natural phenomena such as crossing or selection' (emphasis added).

The Technical Board of Appeal in the present case took the view that the introduction of Rule 23b(5) did not finally settle the question as to the interpretation of Article 53(b). An argument could be made that, unless the previous case law (most notably T 320/87 and T356/93) erred in its interpretation of Article 53(b), this interpretation could not be overturned by a newly drafted rule of the Implementing Regulations.[296] The Board pointed out an anomaly in that, according to Rule 23b(5) EPC, only processes which consist entirely of natural phenomena were considered to be essentially biological processes for the production of plants (Rule 23b(5) EPC). In addition, crossing and selection were given as examples of natural phenomena, when, in traditional plant breeding, the systematic crossing and selection would not occur without human intervention.[297]

It is relevant to note that despite a review of the legislative history behind Article 53(b) and Rule 23b(5) EPC, the Technical Board of Appeal felt unable to reach a decision regarding the interpretation of the exclusion to patentability. Hence, the Technical Board of Appeal referred the following questions to the Enlarged Board of Appeal:

1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?

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[296] Kilburn & Strode, 2007. New EBA Referral from T 0083/05 – Breadth of Exclusion under Article 53(b), Available at: <
http://www.kstrode.co.uk/news/NewsDet.asp?RID=267&NewsType=Current> [Accessed 14 October 2008]
[297] *Supra*, note 247, pp. 36-37 of the decision.

2. If Question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?[298]

As at 1st December 2010, this Enlarged Board of Appeal Decision is currently pending under the reference number G 2/07.[299] It is interesting to note that the review of case law relevant to the issue at hand identified that the mere requirement of human intervention in itself in a non-microbiological process was not necessarily sufficient for a process to not be 'essentially biological', but significant technical modifications to a process has been held to be sufficient. However, there has to date not been a decision which deals explicitly with the limits of the exclusion.[300]

To sum up, the ruling of the Enlarged Board of Appeal will serve as a case law for all further patents on similar issues. It remains to be seen whether this referral will shed any light on this exclusion and the contradictory guidance regarding its interpretation. At this juncture, it is worth noting after starting the *Plant Bioscience Limited* case in 2007, a second case related to 'essentially biological processes for the production of plants and animals' under Article 53(b) EPC was forwarded to the Enlarged Board of Appeal of the EPO in May

[298] *Ibid.,* p. 2.
[299] Refer < http://www.epo.org/patents/appeals/eba-decisions/pending.html> for 'Referrals pending before the Enlarged Board of Appeal - Status: 9.5.2008' [Accessed 02 July 2010]
[300] MCDONALD, Chris, 2007. EPO may Exclude Essentially Biological Processes for Plant Production, Available at: < http://www.withersrogers.co.uk/content/view/134/45/> [Accessed 14 October 2008]

2008. The patent on tomatoes was owned by the Ministry of Agriculture of the State of Israel. The decision of these two cases will be considered in consolidated proceedings by the Enlarged Board of Appeal.[301] Together with the first case (G2/07) this second case (G1/08) are hoped to become precedent for the question of patentability of 'conventionally' bred plants and animals in Europe.

(vi) *Monsanto Canada Inc. v Schmeiser*[302]

On the premise that the issue of patentability of transgenic plant in Europe is now settled, the issue of the infringement of such a patent is seen as another challenge in this area. The real problem that has arisen with regard to patents that cover plant-related inventions is the issue of infringement through pollen drift, that is drift of patented genetically engineered crops.

The biotechnology company Monsanto developed a *glyphosate*-resistant gene for the canola plant which had the effect of producing canola that is resistant to their Roundup brand of herbicide. Hence, the patent application filed by Monsanto was for a technology that made plants resistant to *glyphosate* herbicides such as Monsanto's Roundup. The patent grants the company the exclusive right, privilege, and liberty of making, constructing, using, and selling the invention in Canada until the patent's expiration on February 23, 2010. Though Canada's Plant Breeders' Rights Act protects the intellectual

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[301] The Enlarged Board of Appeal of the EPO (EBoA), whose primary task is to clarify important points of law under the EPC, will hold public oral proceedings in cases G2/07 ("Broccoli") and G1/08 ("Tomatoes") on 20 and 21 July 2010 in Munich. This is because both cases are concerned with the exclusion of essentially biological processes for the production of plants under Article 53 (b) EPC. A Technical Board of Appeal has referred questions to the EBoA relating to the degree and nature of human technical intervention, which is necessary for that provision not to apply. Refer < http://www.epo.org/topics/news/2010/20100203.html> [Accessed 07 July 2010]
[302] [2004] 1 S.C.R. 902, 2004 SCC 34.

property rights of seed developers, Monsanto felt a patent would provide more protection since it would deny farmers the right to save and re-use seeds containing the company's patented genes and cells. In this regard, it is worth noting the patent would apply to the genes and cells containing the DNA that makes the plant *glyphosate*-resistant; it would not apply to the plant itself.

Monsanto marketed the seed as Roundup Ready Canola. Farmers using the system were able to control weed competition using Roundup, while avoiding damage to the Roundup-resistant crops. Users were required to enter into a formal agreement with Monsanto, which specifies that new seed must be purchased every year, and an annual licensing fee of C$15 per acre be paid. Roundup Ready Canola was introduced in Canada in 1996, and by 1998, it accounted for 25% of the country's canola area.

In 1997, Percy Schmeiser, a canola breeder and grower in Bruno, Saskatchewan, discovered that a section of one of his fields contained canola that was resistant to herbicide Roundup. The origin of these Roundup-resistant plants is unclear, but it is possible that seed blew onto the Schmeiser property from neighbouring farms, where Roundup Ready Canola was being cultivated. A farmhand later harvested and saved the seed from this area, this seed was used to replant in 1998. That harvest was sold for feed. During 1998, over 95% of Schmeiser's canola crop of approximately 1,000 acres (4 km^2) was identified as the Roundup Ready variety.[303]

Monsanto then sued Schmeiser for patent infringement, by keeping Roundup Ready canola seeds and failing to obtain a licence for the canola plants.

[303] *Supra*, note 302, pp.14-15.

Schmeiser maintained that this was accidental. Patents being in federal jurisdiction, the case went to Federal Court. At the Federal Court Trial Division, the trial judge found that Monsanto's patent was valid and infringed by Schmeiser. This finding was upheld by the Federal Court of Appeal. The case was further appealed to the Supreme Court of Canada. On May 21, 2004, the Supreme Court of Canada rendered its decision to uphold Monsanto's claim of patent infringement against Schmeiser. By a narrow 5 to 4 majority, the court found that the patent was valid and that Schmeiser had infringed it.

The Supreme Court held that Monsanto's patent was valid irrespective of whether protection for the gene and cells extended to activities involving the plant. Although Monsanto only claimed protection for the genes and cells, 'a purposive construction of the patent claims recognizes that the invention will be practised in plants regenerated from the patented cells...' [304]

As the trial judge's findings that Schmeiser saved, planted, harvested and sold the crop containing the patented gene and cells were uncontested (although the original plants came onto his land without his intervention), the issue was whether this amounted to 'use' of patented material. According to the majority who found Schmeiser liable for infringing Monsanto's patent, the acts of saving and planting the seed, then harvesting and selling plants containing the patented cells and genes, constituted 'utilization' of the patented material. Furthermore, by cultivating the canola without licence, Schmeiser was deemed to have 'deprived [Monsanto] of the full enjoyment of the monopoly'.[305]

[304] *Ibid.*, para 119, pp. 53-58.
[305] *Supra*, note 302, para 71, p.38.

Interestingly, the majority interpreted existing case law relating to mechanical inventions as supporting the proposition that even if a product as a whole is not covered by a patent, if an important part or component of the product is patented, exploitation of the product may still result in infringement. Patented components are not usually intended to be used in isolation. Therefore, the judges maintained that infringement did not require use of the gene or cell in isolation.[306]

Moreover, under a purposive interpretation of the claims, the majority found that the purpose of the patent was to sell plants or seeds containing the modified genes. They also said that Schmeiser had failed to rebut the presumption of use, as he had actively cultivated Roundup Ready canola as part of his business operations. They maintained that infringement does not require the use of Roundup, to account for the 'stand-by' utility of the herbicide tolerant trait (that is whether or not a farmer sprays Roundup, cultivating Roundup Ready canola means that the farmer may in future spray and benefit).[307]

Based on the Supreme Court's judgment, it is thus submitted that the presence of one patented gene in effect confers control over the entire plant, something that Monsanto cannot actually patent. Interestingly, in so accepting this 'expansive' conception of patents, the five judges seem to contradict their own 2002 decision, which saw the Supreme Court ruling that higher life forms cannot be patented in Canada[308]. In *Schmeiser's* case, these judges ruled that

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[306] *Ibid.*, p.4.
[307] *Ibid.*
[308] *Harvard College v. Canada (Commissioner of Patents)* [2002] 4 S.C.R. 45, 2002 SCC 76.

higher life forms containing a single patented gene are effectively the property of the owner of the single patented gene.

In this regard, many perceive the majority decision in Monsanto to be inconsistent with the Supreme Court of Canada's holding in *Harvard Mouse*. However, the majority in Monsanto argued that their decision was, in fact, consistent with *Harvard Mouse*, noting that the gene and cell claims in Monsanto's glyphosate-resistant plant patent were analogous to the plasmid and somatic cell culture claims which had been allowed by the Commissioner of Patents in Harvard's patent for a genetically modified 'oncomouse'. It was only the claim for the 'oncomouse' itself, as a higher life form, which was denied, and Monsanto did not claim modified plants in its patent. Notably, both the majority and minority in Monsanto agreed that the claims in Monsanto's patent were valid.

At this juncture, it is submitted that the truly difficult problem which had not been anticipated from the decision of Harvard Mouse was how to draw a line between non-patentable higher life forms and a patentable genetically modified cell. Essentially, higher life forms are not patentable, but their cells are; and since higher life forms are composed of cells, a patent on the cells of plant of animal would effectively give control over the plant or animal itself. An order for destruction of infringing plant cells, for example, would necessarily require destruction of the entire plant.[309]

[309] SIEBRASSE, N., Comment on *Monsanto Canada Inc. v. Schmeiser*, Available at :< http://law.unb.ca/Siebrasse/Download/Schmeiser%20Comment.pdf> [Accessed 23 June 2010]

Nevertheless, Schmeiser won a partial victory, when the court held that he did not have to pay Monsanto his profits from his 1998 crop, on the basis the presence of the gene in his crops had not afforded him any advantage and he had made no profits on the crop that were attributable to the invention.[310]

Many members of the biotechnology industry welcomed the decision. Obviously, the majority in Monsanto recognized that many biotechnology inventions would only receive the full benefit of patent protection if the scope of the patent extended to genetically modified organisms as a whole. The majority asserted that it had only interpreted the Patent Act as it perceived it, and any amendments would be open to Parliament to pursue. Until and unless Parliament enacts amendments to the Patent Act that clarify issues on patentability of higher life forms (in particular transgenic plant) in Canada, the biotechnology community may need to rely on the distinction outlined by the majority judgment in Monsanto in support of patent infringement claims involving higher life forms.

However, the decision still leaves some issues unresolved with respect to the scope of protection afforded to biotechnology-related inventions. The court, while confirming the validity of Monsanto's patent on the transgene and modified cells, did not rule on the validity of patents on life forms, or whether it is right or wise to genetically modify plants. Obviously, the 2002 Supreme Court decision that higher life forms, such as plants, are non-patentable still stands. After all, Monsanto did not claim patent protection over a GM plant, only the modified genes and cells and the process for making them.

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[310] *Supra*, note 302, p.48.

Having said that, what is now clear is the effect of the judgment; that a patent owner's rights on a patented gene and cells extend to the (non-patentable) plant in which it is found, if the alleged infringer is judged to have used the patent; in *Schmeiser's* case, by saving, planting, harvesting and selling in a commercial context. In short, the practical effect of *Schmeiser's* case was to render *Harvard Mouse's* prohibition of patenting of higher life forms almost entirely ineffectual.

Another unresolved issue is perhaps Monsanto's responsibility for its uncontainable technology, which was not considered by the judges in this case. It remains to be seen whether patent owners like Monsanto and other companies would be held liable for contaminating the farmers' fields; whether they should be accountable for their technology?

The fact that the court found that Monsanto was owed none of the value of Schmeiser's crop may, however, be an important counter to the finding of patent infringement. Growing and re-growing contaminated seed may not oblige a farmer to pay Monsanto anything, presuming that they are not benefiting from the herbicide tolerant gene by spraying Roundup.

This case is significant in the sense that it has attracted attention worldwide, raised awareness globally on many issues such as patents over transgenic plants and living organisms, GM crop contamination as well as the need to protect farmers' rights.

The decision of the majority provides support to the Canadian biotechnology industry in a number of ways. First, by acknowledging that patents on modified genes, vectors, and cells containing modified genes have effect beyond the genes, vectors, and cells themselves, patents held by biotechnology researchers have greater scope and therefore greater value.

Second, the effective scope of patent protection in Canada is now arguably similar to the scope of protection available to patentees in other industrially developed countries and regions, such as the United States and Europe. Therefore, the Canadian biotechnology industry can compete on a global level.

Third, the majority acknowledged that the purpose of the patent obtained by Monsanto was to maintain a monopoly over the production and sale of glyphosate resistant plants. Arguably, if no protection were afforded to biotechnology inventions involving plants (or other higher life forms), there would be significantly less incentive to conduct research and invest in this area of technology. If an inventor has no recourse against unauthorized use of his invention, there is little reason to invest in such technology.[311]

Fourth, the judgment provides an excellent balance between allowing effective enforcement of patent rights without unduly burdening the user. The majority in Schmeiser adopted a broad approach to defining patent 'use', but a narrow approach to remedy. This point is essential to the problem of the 'innocent bystander' who finds patented plants have entered onto his land without his knowledge. The Court was very clear that the issue was not raised on the facts, as Schmeiser was an intentional user, but the principles which were

[311] LAW, G.S. and MARLES, J.A., 2004. Monsanto v Schmeiser: Patent Protection for Genetically Modified Genes and Cells in Canada, *Health Law Review*, 13 44-47, Available at :<http://www.law.ualberta.ca/centres/hli/userfiles/13-1-07_Law-Marles.pdf> [Accessed 25 June 2010]

established by the decision are nonetheless directly relevant. The broad definition of 'use' indicates that an innocent bystander would be strictly considered an infringer, but the more stringent requirements at the remedial stage suggest that an innocent bystander has little or nothing to fear in the final result. The welcome conclusion is that the plight of the innocent bystander under existing law is not nearly so perilous as is sometimes supposed.[312]

It worth noting at this juncture that there have been a number of other litigations by Monsanto in asserting their patent rights, but the courts in other jurisdictions seemed to have another approach in deciding the issue. For example, on 6th of July 2010, the European Court of Justice (ECJ) handed down their judgment in the case of *Monsanto Technology LLC v Cefetra BV and Others* (Case C-428/08), a referral to the ECJ from the Rechtbank's-Gravenhage of the Netherlands. This case is of particular significance for patentees in the biotech industry since it has provided one of the first opportunities for the ECJ to address the scope of gene patents in Europe in light of Directive 98/44/EC (the Biotech Directive). Importantly, the ECJ, following the Advocate General's Opinion, has concluded that the scope of protection for gene patents, as it relates to products incorporating the gene sequences claimed, does not extend to situations wherein the sequence does not perform the function for which it was patented. In another case (UK), *Monsanto v Cargill* [2007] EWHC 2257, the Judge found as a fact that the gene sequence was present in the imported soymeal, but held that the patent was not infringed. These two cases seem to suggest the fact that decision by

[312] SIEBRASSE, N., *supra*, Note 309.

the Supreme Court of Canada in *Schmeiser's* case is just too extensive or too expansive to be adopted in other similar cases elsewhere.

All in all, the key principles as derived from the judgment are essentially supportive towards the biotechnology industry as a whole, hence developing countries like Malaysia may follow suit by adopting the similar approach in patenting of agricultural biotechnological inventions, in order to enhance and strengthen its current patent laws with the aim of accelerating its biotechnology growth.

2.9 Patentability of transgenic plant in Europe: the current position

After a thorough discussion and analysis of the case-law by the EPO and some landmark cases across Europe, it is submitted that the issue of patentability of agricultural biotechnological inventions, specifically plant varieties and transgenic plants, is still not free from uncertainties. Most of the cases were decided on their own merit, hence though, the principle and reasoning from the judgment serve as a useful guidance in this area.

Based on the black-letter law, Article 53(b) EPC spells out that plant or animal varieties or essentially biological processes for the production of plants or animals are excluded from patentability, whereas microbiological processes or the products thereof are not.

Early case law of the Technical Board of Appeal at the EPO such as *Plant Genetic Systems*[313] showed that a broad claim in a patent application to a transgenic plant applied to plant varieties and was excluded from patentability.

[313] *Supra*, note 24.

However, later cases showed that a claim directed to transgenic plants may not be excluded from patentability even if plant varieties fall within the scope of the claim. This is the decision by the Enlarged Board of Appeal decided Case G 1/98 *Novartis/Transgenic plant*.[314] Hence, it is now possible to patent a plant variety in Europe, by directing the claim onto transgenic plants (that embrace plant variety) rather than claiming over plant varieties *per se*.

The decision in the *Novartis* application significantly overturned the earlier decision and interpretation of the EPC that was based on the *Plant Genetic Systems* decision and exemplified the state of patent law with regard to GM plants: GM plants can be protected by a patent in Europe if the invention is not limited to a single variety. Single varieties that have been generated using GM technology can be protected under the plant breeder rights legislation.

In an effort to clarify the law as to what is patentable in biotechnology and also to harmonize the law in the European Union member states, Directive 98/44/EC of the European Parliament and the Council on the Legal Protection of Biotechnological Inventions (European Directive) came into force in 1998 after 10 years of debate and political struggle. Although this directive remains controversial among the member states, it clearly represents a much-needed landmark in patent law relating to biotechnology inventions. Again, this directive deems plant and animal varieties non-patentable. Although the concept of a plant variety is defined as in the UPOV Convention, the Directive further specifies that a plant variety is defined by its whole genome. Accordingly, a plant grouping that is defined by a particular gene only is not considered to be a plant variety.

[314] *Supra*, note 25.

An amended version of the EPC implementing regulations came into force on 1 September 1999, in which certain provisions of the European Union Directive were incorporated, including the definitions of a plant variety as specified in the UPOV Convention and the Community Plant Variety Rights. Under Rule 23c(b) EPC, inventions are patentable if they concern plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety.

It is interesting to note the pro-patenting attitude in respect of protecting biotechnological inventions in Europe based on the stance taken by the EPO in *Novartis*. Nevertheless, the *Novartis* case received an unusual amount of public attention, which reflected the controversial way in which the public perceives GM plants. The EPO received more than 600 letters from individuals and organizations expressing concerns about the grant of patents that relate to living matter. Many expressed the view that such patents would be contrary to *'ordre public'* or morality and are therefore excluded from patentability (Article 53(a) of the EPC). The Enlarged Board of Appeal argued that the contracting states of the EPC have not agreed on condemning the genetic engineering of plants *per se* because it is contrary to morality. The Board also referred to Directive 98/44/EC of the European Parliament, which considers the protection of biotechnology inventions to be essential to encourage investment in the field.[315]

[315] FLECK, B., and BALDOCK, C., 2003. Intellectual property protection for plant-related inventions in Europe. *Nature Reviews Genetics 4, 834-838*, Available at: <http://www.nature.com/nrg/journal/v4/n10/full/nrg1184.html#B5> [Accessed 23 June 2010]

The landmark case in Canada (*Schemieser*'s case)[316] which in effect legally acknowledged that patents on modified genes, vectors, and cells containing modified genes do extend to transgenic plant in which the genes is found, marks an interesting yet positive development for biotechnology industry. Nevertheless, the legal implication from the case only took effect in Canada alone. The Supreme Court of Canada apparently recognized that many biotechnology inventions will only receive the full benefit of patent protection if the scope of the patent extends to genetically modified organism as a whole. Although the approach of Canadian courts is somehow different as compared to the EPO, it renders the same effect as it is now possible to protect transgenic plants in Canada, not by patenting the plant *per se,* but by way of patenting the plant cells and genes, which practically and ultimately make up the whole transgenic plant.

To sum up, patents over plants are now permitted under the EPC as patents can be granted for inventions that cover more than a single variety. This observation is built on the interpretation of the patentability of plant-related inventions in Europe on the basis of the amended EPC, the European Directive and recent European case law. However, it is important to bear in mind that any patent application that is directed to a plant-related invention must also fulfill other criteria that are laid out in the EPC, such as novelty, inventiveness and sufficiency of disclosure. For example, a controversial 'soya' patent owned by Monsanto (Patent EP301749 (1998)) was limited after it had been granted, owing to opposition from third parties. The soya patent concerned a method of genetically engineering plants, in particular soybean, by introducing a foreign gene through particle mediation. The patent also covered soybean seeds and

[316] *Supra* Note 302.

tissue that were obtained through this method. Under European patent law, a patent description must be sufficiently clear and complete so that it can be carried out by another party with a general knowledge of the field concerned. The Opposition Division found that the soya patent did not meet this requirement for sufficiency and limited the patent to soybean plants only, rather than to any kind of plant engineered using particle mediation.[317]

2.10 The interface between patent and plant variety protection

PVP is conceptually close to patent rights but differ insofar as the rights granted to commercial plant breeders are more circumscribed than under patent laws. Hence the interface between patent protection and that offered under the plant varieties legislation is a thorny issue, made more topical since the UPOV 1991 removed the former ban on double protection. It has been viewed by some scholars[318] that the two systems should be viewed as complementary, operating in two different judicial niches, rather than as competitors for the same niche.

The key issues in relation to IPR regimes over plants include the balance between the rights and obligations of breeders and farmers, and in creating a mutually reinforcing system. In this regard, patent rights and PVP in plant breeding should be seen as part of a wider strategy for developing an efficient and equitable agricultural biotechnology industry.

Plant variety rights essentially represent a system of private property rights broadly similar to a patent system, but differing from such a system in many

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[317] FLECK, B., and BALDOCK, C., *op.cit*.
[318] One of them is Andre Heitz, a senior counselor of UPOV, *supra*, note 17.

respects because it has to deal with the problems of living plant material. The self-reproducing capability of a plant, through the medium of seed or vegetative propagation, makes a new variety particularly vulnerable to unauthorized exploitation. The former share a number of characteristics with patent rights: they provide exclusive commercial rights to the holder, reward an inventive process, and are granted for a limited time after which they pass into the public domain. The term or duration of a patent is 20 years from the date of filing of the application[319], whereas for plant variety rights, the period of protection has evolved over time but always with the idea that the rights conferred expire at the end of a specific period of protection. Under UPOV 1978, the period of protection is of a minimum of 15 years. For vines, forest trees, fruit trees and ornamental trees, the minimum is 18 years. UPOV 1991 extends the minimum period from 15 to 20 years. For trees and vines, the minimum is of 25 years.[320]

The rights conferred to plant breeders differ from patent rights in several aspects; the scope, exceptions, administration, and assessment before the rights can be granted. These distinctions will be dealt with in turn.

Firstly, in relation to scope and requirement of the rights, patents serve to protect any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.[321] The term 'new' or 'novelty' under patent law denotes that such an invention has not been made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the patent

[319] Article 63 EPC.
[320] Article 19 UPOV 1991.
[321] Article 52 EPC.

application.[322] In contrast, as far as plant varieties are concerned, they are only entitled for PVP if they fulfill the four basic criteria of novelty, distinctness, stability and uniformity or homogeneity, as provided under UPOV. At this juncture, it is important to note that the concept of novelty differs from that under patent law. Under UPOV, a variety is novel if it 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. Novelty is thus defined entirely by commercialization and not by the fact that the variety did not previously exist. UPOV gives a specific time frame for the application of novelty. To be novel, a variety must not have been commercialized in the country where the application is filed more than a year before the application and in other member countries more than four years (six years in the case of trees and vines).[323]

Besides novelty, patent law also requires a patentable invention to fulfill the criterion of inventiveness. Hence, an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.[324] In other words, patents serve to protect novel results which are non-obvious. In order to ascertain whether or not the invention is obvious to one skilled in the art it is necessary to demonstrate the steps taken in arriving at the invention. The disclosure of the steps taken in order to arrive at the final result is requisite if the applicant is to succeed in showing that what s/he has done is inventive. This is shown by describing what was known before and demonstrating how what the inventor did was not an obvious step forward given what had been known before.

[322] Article 54 (1) and (2) EPC.
[323] Article 6(1) UPOV 1991.
[324] Article 56 EPC.

In contrast, the plant variety rights system is not intended to protect non-obvious results. Most plant breeding activity involves trying the obvious - if breeders were required to show that what they had done would not be obvious to a person skilled in the art then few if any rights would be granted. The rationale for the grant of a plant variety right is therefore not to protect inventiveness. There is no need for the breeder to disclose information about how the variety was developed the variety as he or she does not have to prove that their decision to pursue a particular line of research was unobvious.

The key rationale for the grant of a plant variety right is the protection of the time invested in producing a new variety which is distinct from others of the same species, and which, over time, remains uniform and stable following reproduction.[325] The requirement of uniformity and stability for a plant variety before protection can be granted poses some practical difficulties, as these requirements can only be proved after a certain period of time. In contrast to the paper assessment undertaken to determine whether an invention is patentable, a plant variety is subjected to two years of practical trials before the right is granted. These serve to show whether or not the variety is actually distinct, uniform and stable as opposed to simply relying on a written description provided by the breeder. The trials are undertaken by the granting offices in conjunction with breeding institutes, such as the UK's National Institute of Agricultural Botany (NIAB).[326] In Malaysia for instance, the period required for growing tests to prove uniformity and stability varies depending

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[325] LLEWELYN, Margaret, 2002. *Intellectual Property and Biotechnology: A European Perspective*. [online]Available at: < http://www.iprsonline.org/resources/biotechnology.htm > [Accessed 01 December 2008]
[326] LLEWELYN, Margaret, *supra*, note 287.

on types of plants, and it may extend up to ten, even to twenty years for plants like palm oil.[327] The protection via PVP would only be available after all those stability and uniformity requirements of a plant variety are satisfied.

In contrast with patent system, a grant of patent for an invention is only based on paper to satisfy the requirements of novelty, involve an inventive step and is susceptible of industrial application. In this regard, the patent system apparently serves as a quicker means in comparison to PVP, as it is able to provide faster protection in terms of time as there is no need to satisfy the requirements of uniformity and stability before a transgenic plant could be afforded with patent protection.

Other than the requirements of the rights as discussed above, the rights conferred to plant breeders differ from patent rights insofar as they provide much more extensive exceptions to the rights conferred than patents. Breeders have exclusive rights to produce or reproduce protected varieties, to condition them for the purpose of propagation, to offer them for sale, to commercialize them, including exporting and importing them, and to stock them in view of production or commercialization. These rights are restricted by a number of exceptions that are compulsory in the UPOV context, on the basis of public interest. The rights of breeders do not extend to acts done privately and for non-commercial purposes, to acts done for experimental purposes, to the use of the protected variety for the purpose of breeding other varieties and the right to commercialize such other varieties as long as they are not essentially derived from the protected variety.

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[327] As confirmed by plant examiners during the interview session carried out on 24th July 2009 at Plant Variety Right Office, Department of Agriculture, Malaysia.

At this juncture, it is noteworthy that the patent system also provides an experimental use exception. This limited exception to the patent-holder's monopoly exists in order to allow for unauthorized application of the patent in particular contexts without the fear of infringement proceedings. Although the content and scope of this exception differs between jurisdictions, the basic concept is that unauthorized use of the patent for experimental or research purposes will not constitute infringement.[328] It has been contended that narrow experimental use exemptions inhibit R&D by discouraging innovators from improving patented inventions and by restricting access to state-of-the-art technologies and research tools without the prior payment of a fee. On the other hand, a broad research exemption may discourage R&D by allowing innovators to design around inventions and develop competing technologies, thus reducing the ability of patent holders to recover returns on their investments. In order to ensure that patent law does not get in the way of new discoveries, thus balancing the interests of patent holders and society as the ultimate users at large, there is real a need of certainties with regard to the boundaries of the exemption.[329]

While the research exemptions are compulsory, there exists a set of further exceptions under PVP which have been progressively reduced over time. The

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[328] For example, under UK Patents Act 1977, Section 60 (5) states that: 'An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if - (a) it is done privately and for purposes which are not commercial; (b) it is done for experimental purposes relating to the subject-matter of the invention'. The similar provision under Malaysia Patents Act 1983 is Section 37 (1) which says that : 'The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research'.
[329] For example, in July 2009, the UK Intellectual Property Office (UK-IPO) attempted to clear up uncertainty and doubt about an exception to patent law for researchers, moving to end a lack of clarity about which acts are illegal and which are allowed. The move follows the very first recommendation of the 2006 Gowers Review of Intellectual Property commissioned by the Treasury. Refer : <http://www.out-law.com/page-9244> [Accessed 04 July 2010].

so-called farmer's privilege falls into this category. Under UPOV 1978, the rights of breeders were circumscribed in such a way that plant breeders' rights did not interfere with farmers' use of the legally obtained protected variety for propagating purposes on their own holdings. Under UPOV 1991, the rights of breeders have been extended to the harvested material of the protected variety and the farmer's privilege has been made optional.[330] These exceptions are essential to ensure that the protection granted does not restrict ongoing research or interfere with the legitimate interests of the agricultural community.

The other point of distinction between patent protection and plant variety rights is in relation to the administration of the rights. Plant variety rights are generally administered by governmental agencies responsible for agricultural matters and not by offices concerned with trade and industry, as is the practice with patents.

Interestingly, PVRs were at first conceived as an alternative to patent rights and it was accepted that the two kinds of intellectual property rights should be kept separate. Thus, under UPOV 1978, member states can only offer protection through one form of intellectual property rights. The grant of a PVR on a given variety implies that no other intellectual property right can be granted to the same variety. Under UPOV 1991, this restriction has been eliminated hence the issue of double protection is finally put to rest.

Notwithstanding these differences as shown in the above discussion, slowly but steadily, PVRs are becoming more similar to rights conferred under patent

[330] Article 15 UPOV 1991.

laws. This is evident after the latest revision of UPOV, in which the scope of PVRs has been expanded to give exclusive rights on the direct exploitation of the plant variety. This latest development made the PVRs more similar to the exclusive rights conferred upon the patentee through patents. This could be linked back to the intention of the PVR system when it was introduced, which was to give breeders broadly similar incentives and opportunities for reward as were available to inventors under the patent system. Besides, as the 1991 amendment introduced the requirement of intellectual property protection for all plant genera and species and extended the duration of the right, it could also be described as a substantial strengthening of protection and an assimilation to the protection under the patent system.[331]

Turning back to the issue of overlapping and interface between these two systems of protection, European law is of particular interest for the interface problems, for it contains a modern piece of legislation, namely the EU Directive on the protection of biotechnological inventions which was enacted, *inter alia*, with the explicit goal of promoting the fruitful coexistence of the patent and PVR systems and which directly addresses relevant interface issues in several of its provisions.[332]

For plant-related inventions and innovations, there remains the question whether the availability of patents and PVRs should be made exclusive, alternative or cumulative.[333] Article 27(3)(b) TRIPS resembles the regulation

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[331] LENBEN, Markus, 2006. *The Overlap Between Patent And Plant Variety Protection For Transgenic Plants: Problems And A Solution*. [online] Available at: < http:// papers.ssrn.com/sol3/papers.cfm?abstract_id=924343 > [Accessed 17 December 2008]
[332] MOUFANG, Rainer, *supra*, note 21, p. 3.
[333] By virtue of Article 27(3)(b) TRIPS Agreement, Member States may exclude from patentability plants and essentially biological processes for the production of plants. However, Members must

of UPOV 1991: neither a special form of protection is required nor is any form of cumulative protection excluded.[334] European law appears to give priority to the PVR system: on the one hand, plant varieties may be protected by national PVRs or by a uniform Community-wide PVR.[335] On the other hand, European patents are excluded for plant varieties and for essentially biological processes for the production of plants.[336] Notwithstanding these provisions, the European legal framework does not really reduce the area of possible overlap between the two systems, since the patent system remains capable of covering plant-related innovations.

At present, European patent law permits patent claims on plant in general, that is claims which are not restricted to one or more specific plant varieties. If, for example, a claim is directed to transgenic plants characterized by the insertion of a specific DNA sequence, it is considered not to be directed to plant varieties *per se* (and thus not hit by the patent exclusion of plant varieties) since plant varieties are defined by their whole genome and, hence, are characterized by a multiplicity of genetic traits. Nevertheless, the scope of protection of such claims may also encompass plant varieties, namely when those varieties contain the specific DNA sequence.

In short, the PVP systems are distinct from patents in allowing an option, under the 1991 Act, for farmers to save seed for subsequent seasons. Under patents, such actions would constitute infringement. The research exemption is one of the key components of PVP, as it promotes the development of new

provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

[334] Article 27(3)(b) TRIPS simply states that plant varieties may be excluded from patentability.

[335] On the basis of the EC Council Regulation No. 2100/94 on Community plant variety rights.

[336] Article 53 (b) EPC and Article 4(1)(a) EU Biotech Directive.

plant varieties by making sure that protected germplasm sources remain available for plant breeding, with the overall goal of encouraging development of new varieties of plants. In terms of cost, PVP applications incur lower cost, as they can typically be completed by a breeder, while patent applications are under the purview of patent lawyers. Although the PVR system could maintain some exclusivity, it could not be avoided that protection gained by patents could be extended to plants belonging to a plant variety as a result of the abstract nature of IP rights. [337]

2.10.1 Is the patent system a better protection for agricultural biotechnology inventions?

Despite the key differences between the patent system and PVP, it is submitted that in comparison to PVP, patent system provides for a stronger protection for agricultural biotechnological inventions. The submission is premised on the patentability requirements that the invention must be new, involve an inventive step and be applicable for industrial application are relatively easier and quicker to be satisfied, as compared to DUS requirements to be fulfilled under PVP. The uniformity and stability requirements in most of the cases consume a long period of time, and protection via PVP would only be obtained once a plant variety could be shown as uniform and stable. In fact, the requirement of stability of a plant variety is one of key distinctions between a variety and what is patentable under the patent system.

On the other hand, under the patent system, an inventor of a transgenic plant (which may embrace a plant variety) has the option to apply for patent protection right from the very early of research stage, for instance a patent on

[337] MOUFANG, Rainer, *supra*, note 21, pp. 3-5.

genes or plant cells or process. This is because patent rules permit the inventor to apply to the patent office at a time when many details of the invention have still to be clarified. Further work and investment may be necessary before the invention becomes a marketable product. This aspect of the patent system provides some security for the inventor, an aspect that is missing under PVP, and may appeal to plant breeders.

The recent developments in plant bioscience and biotechnology have demonstrated that there would not be much difficulty in satisfying those patentability requirements under patent laws. In this regard, a patent application could now be filed and granted in most jurisdictions for the invention in the form of transgenic plant provided the patentability requirements are met.

In terms of scope of protection, it is submitted that the patent regime provides for stronger protection, as it protects what actually is patented. The scope of a patent is defined by its claims and often allows broad coverage of an invention, such as a plant cell containing a new chimeric gene that is applicable to several plant species. From the viewpoint of the inventors, in particular commercial breeders and private firms, patent protection for plant-related inventions is much valued by developers of transgenic plants.[338] One of the practical examples which is relevant to demonstrate the preferability of patent over PVP is the analysis by the Plant Intellectual Property project team

[338] Refer statement made by the executive vice-president of Monsanto in a reaction to the judgment in *Monsanto v. Schmeiser*, *supra* Note 302.

which reported that 'the team could not find anything which did not indicate a growing confidence in the patent system.'[339]

In contrast to a patent, each plant breeders' rights certificate covers a particular variety belonging to a particular plant species. The plant breeders' rights certificate holder may exclude others from selling the protected variety, producing it for sale and making repeated use of the protected variety as a step to commercially produce another variety. Clearly, PVP is specifically designed to protect the propagating material (including seed, cuttings, divisions, tissue culture) and harvested material (cut flowers, fruit, foliage) of a new variety. In this regard, PVP apparently does not give protection to the plant variety as a whole, but rather concentrating on the propagating materials and harvested materials, on the reason that having control over these plant materials would effectively give exclusive rights to the breeders to market the variety, or to license the variety to others. In contrast with patent system which does give protection for patented genes, what being protected under the PVP is not the genes in protected varieties, but rather their unique combination expressed as a phenotype.[340]

In addition, one of the oft-cited features of PVP apparently lies in its exemptions, such as the research exemptions and farmer's privilege. These exemptions are aimed to balance the interests of breeders as the inventors of new plant varieties and farmers as the users of the protected varieties. At this juncture, it is to be stressed that like PVP, the patent system also provides for

[339] The Plant Intellectual Property (PIP) Project was carried out from October 1998 until 2001 by the EU as part of the Fourth Framework Programme. Refer LLEWELYN, Margaret and ADCOCK, Mike, supra, Note 27, at p. 411.
[340] Phenotype denotes the appearance of each variety, based on the DUS criteria.

research exemptions in order to balance the rights and interests of inventors and society. Although the scope and boundaries of the exemptions under patent law are somehow uncertain, but as far as the European laws are concerned, the extent to which experimental use of patented inventions is permitted in Europe is currently governed by national patent laws.[341] The provisions and availability of research exemptions which extends to acts done for experimental purposes relating to the subject matter of the patented invention provides a counter-argument for supporters of PVP, as patent system also provides for such exemptions which are available under PVP.

2.11 Conclusion & Contribution

In summary, the exclusion from patentability for plant varieties has to be seen in relation to the UPOV Convention: plant varieties could and should be protected under this regime and this should remain as an option in the hands of breeders or inventors, whereas other plant-related inventions, which may also encompass plant varieties, not protectable under UPOV, should be patentable as any other invention under patent laws. Irrespective of Article 53(b) EPC, the EPC as a whole is not opposed to forms of alternative or even cumulative protection for plant varieties. Having said that, the issue remains interesting and relevant in dealing with the international context of Article 53 EPC, as patent law is not regarded as absolutely unsuitable for the protection of plant-related inventions on an international level. Neither TRIPS nor UPOV hinders the protection of plant varieties by patent law.

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[341] Art. 64 (1) of the European Patent Convention (EPC) provides that the rights conferred by a European patent in all designated countries to which the European patent extends shall be the same as those conferred by a national patent granted in that state. Article 64 (3) of the EPC provides that any infringement of a European patent shall be dealt with by national law. Thus no provision regarding defences to infringement is found in the EPC.

The case law in Europe seems to demonstrate the on-going tension in the interaction between patent law, and PVP legislation. Interestingly, the hybrid nature of the dual system seems to be working well. Therefore, it could be concluded that generally, based on the case law, the European patent remains an option for plant-related inventions.

As far as Malaysia is concerned, the development and scenario in Europe with regard to the issue of patentability of plant-related inventions plays an important role in guiding and shaping a better patent system in the country which suits the local breeding industry and is conducive for the agricultural biotechnology growth. Chapter Six will incorporate a detailed discussion on ways forward for Malaysia in enhancing its current patent laws and PVP in order to compete at a global level.

Chapter 3

Agricultural Biotechnology: Patent and Plant Breeder's Rights Protection in the United States

3.1 Introduction

Development of a new plant cultivar or variety requires a large input of time and effort. Some companies estimate that it takes ten to fifteen years to develop a new variety. Hence, in order to recover the costs of R&D, the breeder or inventor may seek to obtain exclusive marketing rights for the new variety. In this regard, one of the most important issues regarding agricultural biotechnology is the legal environment in which seeds are going to be produced and traded. Hence, in the discussion on the patentability of agricultural biotechnological inventions, one often refers to the United States of America, where the legal framework appears to be much more favourable for biotechnological inventions. In fact, the intellectual property regime in the U.S. has been described as one of the 'friendliest' in the world for biotechnology inventors.

This chapter on the legal protection of agricultural biotechnological inventions in the U.S. is significant for the purpose of the research in the sense that the U.S. system represents the opposite approach in comparison to the European approach. The different approaches of these two important jurisdictions of IP legal framework is understandably justifiable on the basis of different size of the seed industry, nature of farming activities as well as research and development as undertaken by public or private institutions. The U.S. patent system in protecting plant innovation is relevant and useful as a guide for developing countries like Malaysia towards enhancing its own patent regime.

Nevertheless, one of the major concerns which is worth noting is the fact that the U.S. as a developed country has moved towards private funding and increased patenting in modern agricultural biotechnology, whereas Malaysia as a developing country is still depending on public funding to develop its biotechnology industry.

In this chapter, the current IPR legislation in the U.S. will be discussed in considerable detail, namely the Plant Patent Act (PPA) of 1930, the Plant Variety Protection Act (PVPA) of 1970 as amended in 1994, and the Patent Act of 1952. The chapter commences with a brief discussion on the history and background of the U.S. statutory laws in providing protection for biotechnological inventions, which ultimately shapes the current legal framework and the American patent laws. The chapter follows with the discussion on the patentability requirement under the U.S. patent laws, as well as plant variety protection system, with relevant comparisons of the three forms of legal protection.

The other part of Chapter Three is devoted to examining the recent developments in the patent protection of plant-based technology in the United States, and this includes a discussion of decided cases on the issue of patent for agricultural biotechnological inventions. Controversies revolving around plant patents are also discussed briefly.

Chapter Three proceeds further to articulate the comparison of the U.S. and European approaches in protecting agricultural biotechnological inventions. This part of the discussion is important as these two legal systems represent two major jurisdictions with different approaches in their IPRs for plant innovations.

The final part of Chapter Three is devoted to insights as to the relevancy of the U.S. system to Malaysian IP laws. Malaysia as one of the developing countries has taken active efforts towards developing its IPRs legal system, but the question as to what extent the U.S. practice and approach in protecting their agricultural biotechnological inventions is useful to improve laws in Malaysia remains to be seen.

3.2 Brief history and background of the U.S. statutory laws for agricultural biotechnological inventions

Since its creation more than 200 years ago, the U.S. patent system has played an important role in stimulating technological innovation by providing legal protection to inventions of every description and by disseminating useful technical information about them. Throughout its history the patent system has had to adapt to evolving conditions, and it continues to demonstrate flexibility and responsiveness today.[342]

The U.S. Constitution authorizes Congress 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…'[343] Congress' first legislation implementing the Constitutional provision came during the First Congress, when it enacted the Patent Act of 1790. This law formed the basis

[342] MERRIL, STEPHEN A., et al. eds., 2004. *A Patent System For The 21st Century*. Washington, DC : National Academies Press., p.1.
[343] U.S. Constitution Art I, § 8, cl. 8.

for patents within the U.S., creating general requirements of novelty, utility, non-obviousness and enablement/description.[344]

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. Before 1930, the federal government denied patent protection for plants and animals.[345] The denial was on the basis that plants, even those created by man, were considered 'products of nature' and were therefore not eligible for patent protection. Under the doctrine of 'product of nature', breeders' products, even those artificially bred, were not the results of a creative process and hence were not inventions as such.[346]

Even where a biological invention did not constitute a 'product of nature', the claim typically could not sufficiently describe the invention in accordance with the written description requirement. As the patent system, for various reasons as discussed above, was considered an inappropriate method of protecting new plants, there was an imminent need for special legal protection systems for plant breeding in the U.S.

In response to pressure from the nursery industry to curb competitors' reproduction of valuable plants via grafting, finally in 1930, the U.S Congress

[344] Refer 35 U.S.C. § 101 (2000).
[345] *Ex parte Latimer*, 1889 Dec. Commn. Pat. 123 (1889).
[346] OVERWALLE, Van Geertui, 1999. Patent Protection For Plants: A Comparison Of American And European Approaches. *J.L. & Tech*., 39, 143.

took the initiative in patenting plants with the introduction of identical bills into the House and Senate, proposing to remove the 'product of nature' objection and to ease the enablement requirement with regard to plants.[347] The legislation, which came to be known as the Plant Patent Act (PPA), established statutory patent protection for asexually reproduced plants. The rationale is that asexual propagation by divisions or cuttings produces clones, each of which is identical to the parent plant and to all other cuttings or clones taken from the parent, while the production of seeds by cross-pollination does not assure a true new plant variety having the characteristics desired. Hence, under this Act, tubers and seed-produced crops were excluded from the protection. Over the years the courts construed this law quite strictly to apply only to asexual propagation, infringed only when the act of acquiring shoots or plant material is proven, not merely by genetic similarity.[348]

The PPA is an important piece of legislation as it afforded the agricultural industry the opportunity to participate in the benefits of the patent system, which had previously only been enjoyed in the industrial field. It managed to address the concerns of breeders by statutorily recognizing that plant breeders created products that were more than mere products of nature. Supported by celebrated plant breeders like Luther Burbank and inventors like Thomas Edison, the PPA relied on an analogy between new breeder-produced varieties and new mechanical, electrical, or chemical inventions.

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[347] *Ibid*.

[348] DHAR, T., FOLTZ, J., 2007. The Impact of Intellectual Property Rights in the Plant and Seed Industry. *In*: J.P. KESAN, ed. *Agricultural Biotechnology and Intellectual Property: Seeds of Change*. Oxfordshire: CAB International, 2—7, p. 162.

Nevertheless, by prohibiting only asexual reproduction of varieties protected by plant patent, the PPA offered no protection for breeders of seed for commercial grain agriculture. Accordingly, seed saving, and appropriation by competitors, remained legal and commonplace.

At this juncture, it is to be noted that before Congress passed the PPA, plant breeders were unable to simply apply for regular utility patents on new plant varieties due to two main obstacles. First, the Patent Office at the time viewed plants, even newly invented varieties that would not exist but for human intervention, as non-patentable products of nature. In other words, so far as the Patent Office was concerned, there was no difference between stumbling on a new plant in the woods and developing a new plant in a breeding program. Second, plant breeders had trouble providing written disclosures that were detailed enough to satisfy the Patent Act requirements for utility patents.

In 1952, the U.S. Congress passed a new patent act, the 'Utility Patent Act' (UPA)[349], which is still in force today. The 1952 UPA is significant in the sense that it 'rearranged existing statutory provisions and stated in statutory form matters previously recognized only in court decisions and Patent Office practice.' The first Patent Act in 1790 defined subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof.'[350] When the patent laws were codified in 1952, Congress replaced the word 'art' with 'process', due to its broader scope of interpretation, denoting a process, art or method.[351] It is to be noted that

[349] 35 U.S.C. § 1-376 (1994).
[350] Act of Apr. 10, 1790, ch. 7, § 1,1 Stat. 109, 109-10.
[351] 35 U.S.C. 101(b) (2000).

despite the legislation of the UPA, till the end of the twentieth century, the U.S. utility patent statutes excluded patents on living organisms.

By 1970, it became evident to Congress that due to biological advances, true-to-type reproduction was possible for sexually reproduced plants, namely plants derived from a seed. Accordingly, patent protection for plants provided for in the PPA was extended to sexually reproduced plants in 1970 by the enactment of the Plant Variety Protection Act (PVPA) which was modeled on the UPOV Convention. The significant features of the PVPA are *inter alia*, it has a research as well as farmer's use exemption. The research exemption allows the use of PVPA-protected seeds in research, whereas the farmer exemption allows farmers to replant from PVPA-protected seeds they grew the previous year. However, it does exclude the farmer from selling those seeds to other farmers, a practice commonly called 'brown-bag seeds'. With the enactment of the PPA and the PVPA, the debate on protection for plants under the general Patent Act temporarily came to an end in the U.S.

Over two centuries after the passing of the first Patent Act, in a landmark patent law decision, it was held that patent laws enacted by Congress were broad enough to allow a man-made microorganism to be patented. That was in the year 1980 when the Supreme Court stepped into the fray with its 5-4 decision on *Diamond v Chakrabarty*,[352] which held that genetically modified (GM) bacteria could be patented within the scope of U.S. patent statutes. This decision, which was the linchpin to the explosion of biotechnology patents in the late 1980s and 1990s, was nevertheless not clarified as being applicable to

[352] 447 U.S. 303.

plants until 1985 when, in *ex parte Hibberd*,[353] a utility patent application for a type of corn seed, the Patent Office's Board of Appeals concluded that *Chakrabarty* did apply to plants. The utility patent statutes have higher levels of standards for novelty and utility than the PVPA, and have neither a farmer's nor research exemption. Given these changes, after 1985, seed producers had two methods to protect their IP; a PVP Certificate and a utility patent; and could even apply for protection from both property rights.[354]

3.3 Current IPR legislation in the U.S.

The history of IPRs in the U.S. has created a number of different regimes for seed producers and new plant variety breeders. Each type of protection is governed by a specific law which dictates protection for specific types of plant varieties or plant-related inventions. The following discussion presents a brief overview and description of the salient aspects of current IPR legislation in force in the U.S. namely, the PPA, the PVP Certificate and utility patents under the Utility Patent Act (UPA).

3.3.1 The PPA

The U.S. Patent and Trademark Office (USPTO), an arm of the Department of Commerce, manages plant and utility patents.[355] Plant patents can be obtained only for asexually propagated plants (not seed propagated plants). The right to a plant patent stems from 35 U.S.C. 161[356] which provides that: 'Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found

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[353] 227 U.S.P.Q. 443, WL71986 (1985).
[354] DHAR, T., FOLTZ, J., *supra*, note 306, p. 163.
[355] 35 U.S.C. §§ 1, 2, 101 and 161 (1994).
[356] The PPA is now embodied in Sections 161-164 of Title 35 of the U.S. Code.

seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore, subject to the conditions and requirements of this title..'

The PPA thus extends patent protection not only to inventors but also 'discoverers' of eligible subject matter (but only if asexually reproduced). It is to be noted that protection is limited specifically to plants and plants varieties which have already reproduced asexually. This limitation was an inherent part of the PPA and was apparently premised on the perception that plants produced other than asexually could not be produced reliably true-to-type. Asexual propagation includes propagation using vegetative parts such as rooting, cuttings, grafting, budding or tissue culturing, for example.

The limited scope of the PPA, applying only to asexually reproduced plants, ensures that plant breeders reproduce their plants identically in every respect to the parent plant. It is noteworthy that despite the limitation in scope of its application, the PPA 'was the first legislation anywhere in the world to grant patent rights to plant breeders.'[357] Insofar as the patenting of asexually reproduced plants in the U.S. is concerned, both national treatment and the right of priority have been accorded to foreign plant breeders since enactment of the plant patent law in 1930.[358]

The conditions for obtaining a patent under the PPA are considerably different than those under general patent law. For example, the PPA requires the plant

[357] *Imazio Nursery, Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1563 (Fed Cir. 1995).
[358] *Ibid.,* §§ 161- 164 (1994).

variety be 'distinct'[359], rather than 'useful'[360] as required for a general utility patent. Distinct characteristics may include habit, immunity from disease, soil conditions, colour of flower, leaf, fruit or stems, flavor, productivity, storage qualities, perfume, form, ease of asexual reproduction, and defectiveness. It is immaterial whether the characteristics are inferior or superior to those of the existing varieties.[361]

Furthermore, the written description requirements of general patent law are less stringent in the PPA, requiring only a description 'as complete as is reasonably possible'. The U.S. Court of Customs and Patent Appeals has interpreted this provision to mean that there is no enablement requirement in a plant patent application.[362] This is due to the impossibility of producing the patented plant from a description, because it must be asexually reproduced. In fact, prior to the enactment of the PPA, plants were not considered amenable to the detailed description requirement necessary for utility patents. Perhaps for this reason, the PPA specifically exempts plant patents from the detailed description associated with utility patents. Nevertheless, the applicant ultimately bears the burden of clearly and precisely describing those characteristics which define the new variety.[363]

With regard to the other conditions for obtaining a patent, both the PPA and the Patent Act include novelty and non-obviousness requirements. 'Novelty' refers to newness in its conception. The term 'new' has been interpreted not to mean the plant did not exist previously but to mean that the plant did not

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[359] *Ibid*., §§ 161.
[360] *Ibid*., §§ 101.
[361] Refer S. Rep. No. 315-71(1930).
[362] *In re Greer,* 484 F.2d 488, 490-91 (Cust. & Pat App. 1973).
[363] *Ibid*., at 491.

exist previously in a capacity in which it could reproduce itself.[364] 'Non-obviousness' requires that there be actual inventiveness at the time the invention was made.[365]

As provided in 35 U.S.C. 161, the rights associated with a plant patent include the rights associated with a utility patent, and the 'right to exclude' has additional terms provided in 35 U.S.C. 163: 'In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so produced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any part thereof, into the United States.'

Plant applications are subject to the same examination process as any other national application. As such, the statutory provisions with regard to patentable subject matter, utility, novelty, obviousness, disclosure and claim specificity requirements apply.[366] One requirement for a plant patent application perhaps unfamiliar to utility patent practitioners is that the applicant is required to designate a varietal name for the plant variety for which protection is sought. This requirement has been imposed in part to comply with the U.S.' accession to the UPOV Convention, Article 13 of which requires the examiner to examine a varietal name.[367]

3.3.2 The PVP Certificates

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[364] *Yoder Bros., Inc. v. California-Florida. Plant Corp.*, 537 F.2d 1347, 1378 (5th Cir. 1976).
[365] 35 U.S.C. §§ 103 (2000).
[366] 35 U.S.C. §§ 101, 102, 103, and 112.
[367] U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 1612 (8th ed. 2001 rev. 2008).

The U.S. Plant Variety Protection Act (PVPA) of 1970 was intended to give private plant breeders stronger incentives to develop superior varieties. The Act was passed to fill a gap left by the PPA. Plant Variety Protection (PVP) is a form of intellectual property created to 'encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest.'[368] Under the PVPA, patent-like certificates of protection (PVPCs) may be obtained for varieties of self-pollinating crops, such as cotton, soybeans, and wheat.

The Plant Variety Protection Office, an agency within the Agricultural Marketing Service of the USDA, manages the PVPA.[369] The PVPO maintains over two hundred databases constructed from many resources[370] in order to assemble as complete a description for a crop species as is possible so that variety specific comparisons are possible.

To qualify for a PVPA Certificate, the variety must be new, distinct, uniform and stable.[371] These requirements are significantly less strict than those of the general patent law. 'Uniformity' under the PVPA requires that the variety be 'describable, predictable and commercially acceptable,'[372] and 'stability' requires the variety 'remain unchanged with regard to the essential and distinctive characteristics of the variety' upon reproduction.[373] Those requirements reduce the precise written description and enablement requirements.

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[368] Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970).
[369] 7 U.S.C. § 2321 (1994).
[370] For example, national registries, seed catalogues, review boards, etc.
[371] 7 U.S.C. §§ 2402 (a)(1)-(4)(2000).
[372] *Ibid.,* §§ 2402 (a)(3).
[373] *Ibid.,* §§ 2402 (a)(4).

The PVP right granted has a term of 20 years for most plant varieties, and 25 years for tree and vines. The term starts from the date that the certificate is issued. The PVP rights are the rights to exclude others from selling, marketing, conditioning, stocking, offering for sale, reproducing, importing, exporting, or using the variety to produce (as distinguished from develop) a hybrid or different variety. However, the effectiveness of the PVPA is thought to have been limited by the lack of a utility principle, an extremely narrow scope of protection based on measuring phenotypic differences, and a farmer's exemption.

The significant features of the PVPA relate to the exemptions from infringement, which reduce the scope of its protection as compared to those covered under the Patent Act. First, the PVPA allows for a 'Public Interest Exemption', providing that 'the Secretary may declare a protected variety open to use…in order to ensure an adequate supply of fiber, food or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair.'[374] Thus, the exemption authorizes compulsory licensing upon the determination of public need.

The second exemption to the PVPA is the research exemption, which allows for the use and reproduction of a protected variety for plant breeding or other *bona fide* research.[375] The exemption in effect allows anyone to use the protected seed in a laboratory or field breeding research to develop new lines.

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[374] 7 U.S.C. § 2404 (2000).
[375] 7 U.S.C. § 2544 (2000).

Plant breeders dislike this exemption because it allows others to use the protected seed in their research. The exemption permits other researchers to develop new breeds using the protected seed and exploit the investments made by the certificate holder. Thus, a company may apparently take advantage of investment in money and research by the original inventor and reap financial rewards without the inventor's consent.

The third exemption is the farmer's exemption. This exemption allows a farmer to use seed produced from a patented plant for production on his or her farm. The farmer may also sell the seed, so long as it is not for reproductive purposes.[376] The farmer's exemption was significantly diluted when Congress amended the PVPA in 1994. Congress struck the provision which allowed a farmer to sell seed for reproductive purposes to other farmers. Prior to 1994, the farmer's exemption was given much attention and was interpreted to allow farmers to sell seeds directly to other farmers, as long as they only kept and sold enough to replant their own acreage. It is worth noting although breeders enjoy modest protection of their protected plant innovations from competitors under the PVPA, the saved seed exemption prevents PVP Certificate holders from compelling farmers to purchase the protected variety on an annual basis and in this regard, hinders the seed breeders' ability to engage in the monopolistic behavior typical of most IP regimes.

As far as the UPOV Convention is concerned, the U.S. became a member of the 1978 Act of the UPOV convention in 1981 in order to afford U.S. plant breeders protection in other countries. It is to be noted that in 1985, the

[376] 7 U.S.C. § 2543 (2000).

Patent Board of Appeals and Interferences ruled that seeds, plant tissue cultures, and the plant itself are patentable subject matter under the utility patent statute. The legal implication of this ruling is that plant varieties which are protectable under the PVPA are also eligible for patent protection, whereas the 1978 Act of the UPOV convention does not allow double protection for plant varieties.

In 1994, the PVPA was amended to be in conformity with the 1991 Act of the UPOV convention, but still only applies to sexually propagated plants. In 1999, the U.S. signed the 1991 Act of the UPOV convention, and has a reservation under Article 35(2) of the text (which allows plant patents rather than breeder's rights certificates to be granted).

3.3.3 Utility Patents (UPA)

While the U.S. patent law has been amended several times since 1930, certain core principles have remained the same and could not be changed without fundamentally altering the system. The power to create a patent system arises under Article I Section 8 of the Constitution, which authorized Congress to reward innovation by granting monopolies on inventions for a limited time. The power is exercised in Title 35 of the U.S. Code.[377] Hence, other than plant patents under the PPA, utility patents are one of the three types of protection in the U.S. that apply to plants. The modern version of the patent statute became law in 1952. It was the first full revision of U.S. patent law since the Patent Act of 1836. Like plant patents, utility patents are also administered by the USPTO, Department of Commerce. The Patent Act of 1952 is significant as it forms the foundation for all patent protection in the U.S.

[377] 35 U.S.C. (2000).

General utility patents have provided protection for inventions outside the agricultural sector for many years while the USPTO, as has been mentioned in the preceding discussion, refused to apply the general Patent Act to living things, concluding that they were discoveries in nature rather than inventions. Although available since 1793, the use of utility patents in agriculture was traditionally confined to tractors, ploughs and countless other mechanical or chemical inventions. Finally, in 1980, the U.S. Supreme Court, in the landmark case of *Diamond v Chakrabarty*, found that Congress intended the patentable statutory subject matter to include 'anything under the sun that is made by man.'[378] This decision opened the door for the USPTO to issue patents for genetically engineered plants. This is because the interpretation of the Act concluded that general utility patents may serve as intellectual property protection for plant and animal genetics.[379]

Prior to the Supreme Court's decision in *Chakrabarty*, many patent practitioners, and most of the lay community associated with plants and the seed trade, believed that utility patents were not obtainable for plants. This may, in fact, have been the official policy at the USPTO. Nevertheless, utility patents were being granted for methods of treating and breeding plants. In fact, on a few occasions,[380] the USPTO had issued utility patents which contained product claims to plants and seeds.[381]

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[378] 447 U.S. 303, 309 (1980).
[379] For example, in *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Interf. 1987) relying on the U.S. Supreme Court's decision in *Chakrabarty*, the Board of Patent Appeals held that oysters, although they were animals, qualified as patentable subject matter under § 101 of the Patent Act so long was they were made by man.
[380] An early example, Boehm, U.S. Patent 2,048,056, describes a method of hybridizing plants that includes tow-produt-by-process claims which begin 'the plant which...' (Claims 5 and 6).
[381] SEAY, NICHOLAS J., 1989. Protecting The Seeds Of Innovation: Patenting Plants. *AIPLA Q.J.*. 16 418, at p.427.

The Patent Act of 1952 conveys patent protection to 'whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof.'[382] The U.S. Supreme Court, after examining the text and legislative history of the Patent Act, gave the terms 'manufacture' and 'composition of matter' a broad interpretation to include a live, human-made microorganism. The Court reiterated that discoveries in nature are not patentable, but stated that a non-naturally occurring manufacture or composition of matter that is a product of human ingenuity and has a distinctive name, character, and use is patentable subject matter under § 101 of the Act, even if it is living matter. [383]

The broad interpretation of the Act led the USPTO of issuing utility patents for plants, plant parts and seeds. The USPTO had issued nearly 2000 utility patents for plants by the time the U.S. Supreme Court issued a clear ruling that plants were patentable subject matter under the general Patent Act.[384] As far as utility patent is concerned, in order for a plant breeder to obtain the protection under the Act, he or she must show that the plant is new, useful and non-obvious.[385]

A plant is considered new if it was not known or used by others before its discovery.[386] Moreover, to be new, the plant must be 'one that literally had not existed before, rather than one that had existed in nature but was newly

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[382] 35 U.S.C. § 101(2000).
[383] *Diamond v Chakrabarthy,* 447 U.S. 303, at 308-310.
[384] *J.E.M. AG Supply, Inc. v. Pioneer Hi-bred Int'l, Inc.,* 534 U.S. 124, 127 (2001).
[385] 35 U.S.C. § 101-103 (2000).
[386] *Ibid*., § 102(a).

found.'[387] Another condition to qualify for a utility patent is the invention must be useful.[388] The 'product of a patented process is useful if it may serve some identifiable purpose.' The invention's potential for commercial success is irrelevant; the standard is actual and identifiable usefulness.[389] Under the Utility Guidelines, the applicant must demonstrate either a specific, substantial and credible utility, or a well-established utility. A single such names of utility suffices.[390]

Next, a plant must be non-obvious.[391] The 'emphasis on non-obviousness is one of inquiry, not quality.'[392] Non-obviousness requires the invention to entail a degree of skill and ingenuity greater than that possessed by one with an ordinary level of knowledge in the practice or trade.

In addition, the applicant for a utility patent must meet the stringent description specifications of § 112 of the general patent law. An applicant is required to provide ' a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains...to make and use the same.[393] Today, advances in biotechnological knowledge and expertise in genetic modifications have allowed plant breeders to satisfy these demanding description requirements.

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[387] *Yoder Bros., Inc. v. Caifornial-Florida. Plant Corp*., 537 F.2d 1347, 1378 (5th Cir. 1976).
[388] 35 U.S.C. § 101(2000).
[389] *Imperial Chem. Indus, PLC v Henkel Corp.*, 545 F. Supp. 635, at 644-645 (D.Del. 1982).
[390] Refer Manual of Patent Examining Procedure, available at <http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r6_2100.pdf> [Accessed 23 March 2010]
[391] 35 U.S.C. § 101(2000).
[392] *Graham v John Deere Co*., 383 U.S. 1, 17 (1966).
[393] 35 U.S.C. § 112(2000).

A patent issued under the general Patent Act is good up to twenty years and conveys the 'right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, to exclude others from using, offering for sale, or selling throughout the United States, or importing into the United States, products made by that process.'[394]

Utility patents, by prohibiting almost any unauthorized activity using the patented invention, eliminate the PVPA's research 'free-rider' problem.[395] Competitors who develop equivalent plant varieties or even new, distinct varieties derived from the patented seed may be liable for patent infringement.

3.3.4 The issue of joint protection

As living matter was found to be patentable under the Patent Act of 1952, the Patent Act's patentable subject matter apparently overlaps with the subject matter included under the purview of the PPA and the PVPA. At this juncture, the question was whether the availability of one form of statutory protection precludes the availability of protection under another form. By virtue of the text of the Acts and the legislative history, neither of the plant-specific Acts expressly excludes any plant subject matter from protection under the general patent law.

The issue of joint protection using both PVPC and PUP was resolved in December 2001 by the Supreme Court's decision in *J.E.M. Ag Supply Inc. v*

[394] 35 U.S.C. § 154 (2000).
[395] 7 U.S.C. § 2544.

Pioneer Hi-Bred Int'l Inc.,[396] which held that concurrent protection under the PVPA and the utility patent statutes was legitimate. Interestingly, the Supreme Court addressed the differences in the Acts, but found that the differences did not present irreconcilable conflicts.[397] Thus, the different Acts are to be read together.

Hence, as of July 31, 2007, approximately 5,300 utility patents have been issued by USPTO for plant-related inventions. Out of this number, a total of 1,168 utility patents granted to plant varieties that have not been genetically modified.[398] Indeed, the PUP had the greatest effect on securing the strongest method of protection for agricultural biotechnological inventions, suggesting that PVPCs were a lesser form of IP. Nevertheless, contrary to widely held expectations, utility patents and plant patents in plants did not make PVPC obsolete.

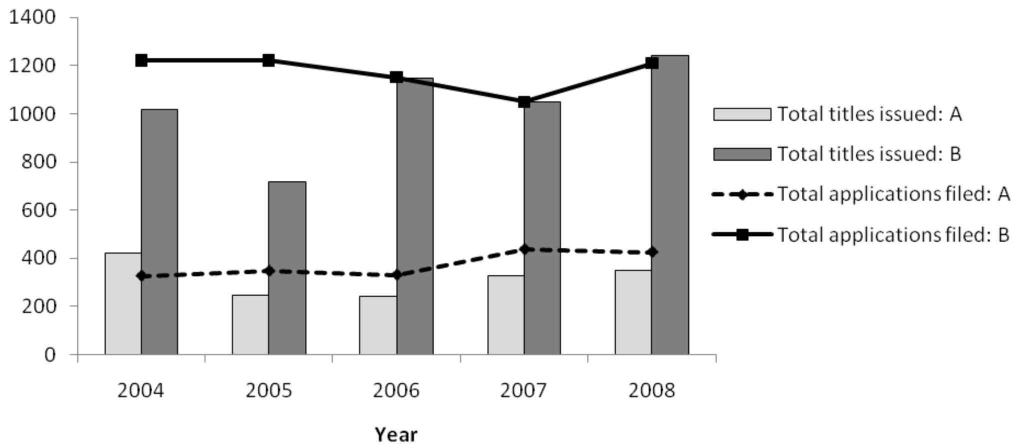
As far as the statistical data is concerned, the comparison of the popularity and actual utilization which is based on the actual number of PVPCs and plant patents applied and granted is shown in the Chart below (Chart 3.1). The number of applications and actual title grants clearly shows the increase in tandem for both types of protection, indicating that some factors have influences in the choice of protection, such as the cost, the application process and procedures as well as the appropriate method of protection for respective inventions and R&D outputs. In this sense, local inventors and breeders as well as foreign companies in the U.S. seem to have a wider option to select

[396] *Ibid.*
[397] *Ibid.*, at 134-137, 142.
[398] Data from USPTO. Refer <http://www.eapvp-forum.org/topics/2010/pdf/20100323_01/d1_04.pdf> [Accessed 08 July 2010].

and decide on which type of protection would better suit their invention. Hence, developing countries like Malaysia would be able to learn and benefit from the current open style system of protection in the U.S., provided that the local small scale and medium size farming communities were not marginalized. Nevertheless, it is noteworthy that the nature of farming activities as well as the stage of R&D and development differ, as Malaysia is still in its infancy as far as biotechnology R&D is concerned.

Chart 3.1

Plant variety protection statistics for the period 2004 - 2008 under the Plant Variety Protection Act (A) and the Plant Patent Act (B)

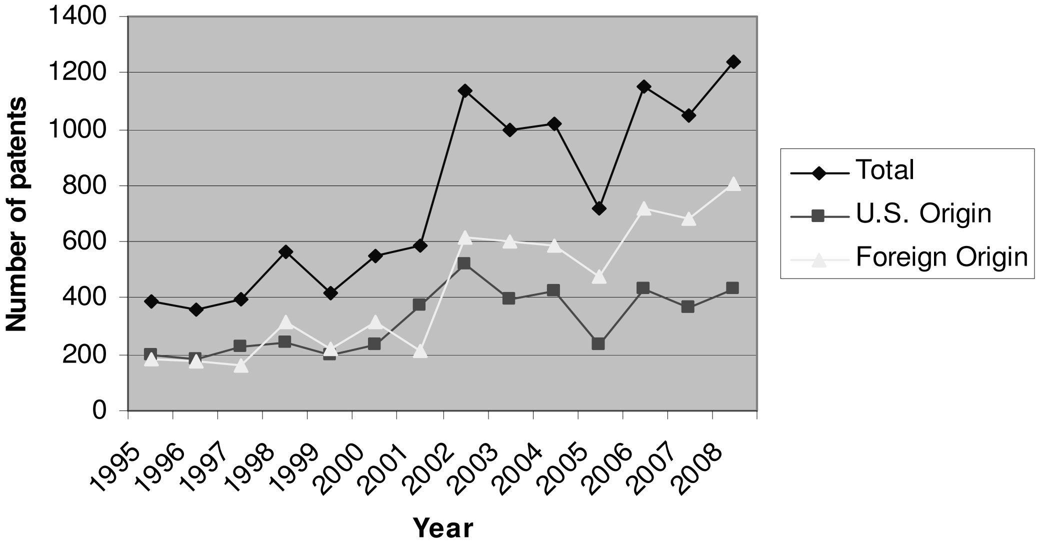


Source: USPTO and UPOV[399]

[399] Refer : <http://www.upov.int/export/sites/upov/en/documents/c/43/c_43_07.pdf> [Accessed 08 July 2010]

Chart 3.2

Number of plant patents granted (U.S. vs. Foreign Origin)



Source: USPTO

Chart 3.2 shows the number of plant patents granted in the U.S. to both U.S. companies as well as foreign companies. The increasing trend in the number of plant patents granted in particular from the year 2000 onwards is foreseeable, in parallel to the growth of biotechnological industry in the U.S. The more interesting finding from the chart is that the plant patents granted to foreign companies outnumbers those granted to U.S. companies themselves. The trend could be attributed to the fact that those plant patents granted to foreign companies are centralized in the horticultural industry which is dominated by foreign players. For example in 2006, the USPTO issued approximately 1,150 plant patents with 432 (38%) awarded to the U.S. inventors. This means that less than half of the plant patents are owned by U.S. companies. The next highest total was the Netherlands with 212 (19%)

plant patents.[400] It is not surprising for Netherlands to own a substantial component of the plant patents in the U.S. as the country is the world leader in horticultural and ornamental plant breeding.

In fact, asexual reproduction in flowering plants is common. Other than those plants that propagate asexually via vegetative production,[401] many different seed plants utilize one of a number of different methods of this form of reproduction. In this regard, it is clear that horticultural breeders and exporters like those from Netherlands and Germany choose to protect their plant inventions under plant patents. The protection afforded by a plant patent apparently is very popular as it has managed to attract many foreign companies to protect their agricultural biotechnological inventions via this system.

The number of plant patents which have been granted to top six foreign applicants is represented in the Chart below (Chart 3.3).

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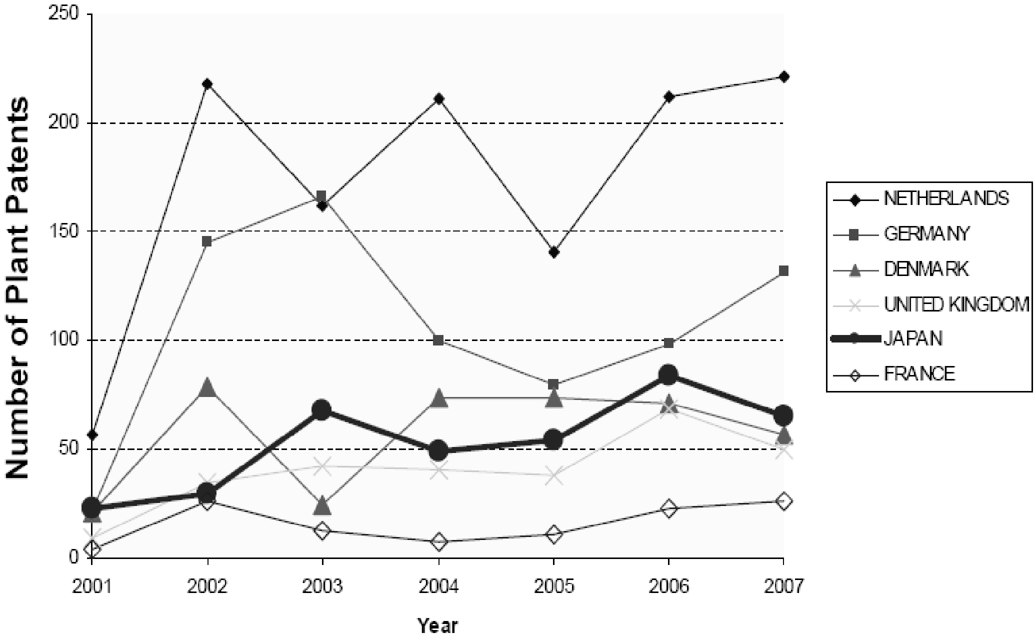
[400] Source : USPTO < http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm>, <http://patentlibrarian.blogspot.com/2007/06/plant-patent-article-in-gardening.html> [Accessed 08 July 2010];

[401] The principal types of vegetative reproduction structures are bulbs, corms, rhizomes and runners.

Chart 3.3

Number of plant patents (PPA) granted to top six foreign applicants

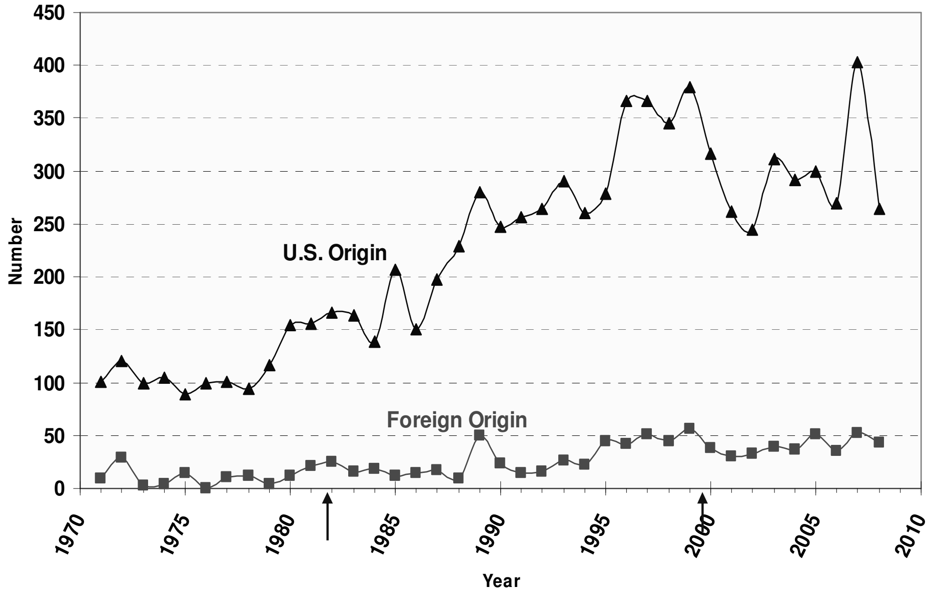


Source: USPTO

Despite the argument that the simultaneous existence of three partially overlapping forms of protection complicates the understanding of intellectual property protection to plant varieties, having such a system inevitably contributes to much wider options for both local and foreign inventors and breeders in the U.S.

Chart 3.4

Number of PVP Applications Foreign Origin vs. U.S. Origin



Source: USPTO

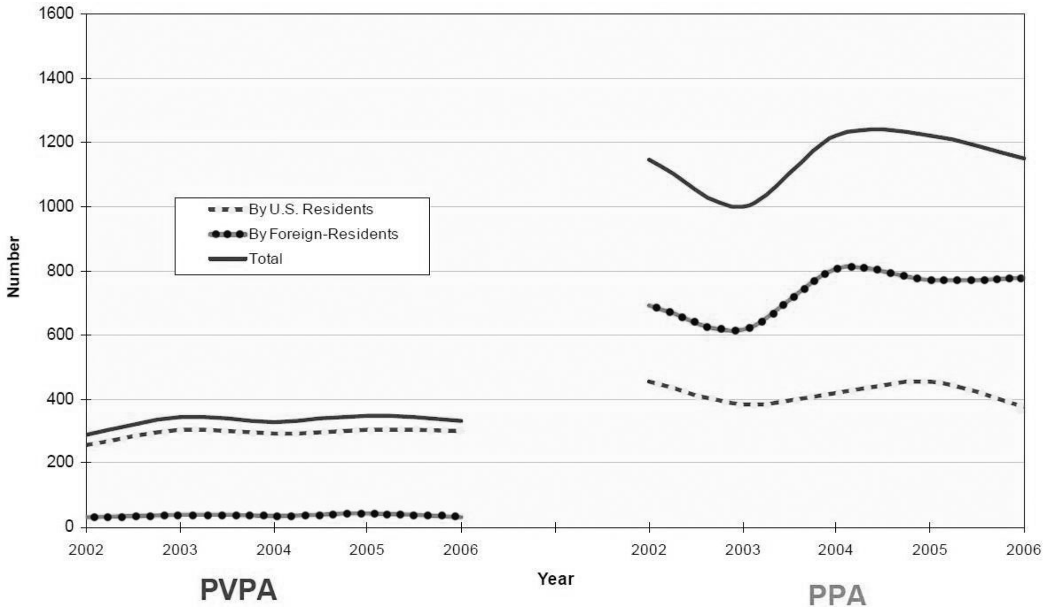
Note: The arrows indicate the year that the U.S. joined the 1978 Act and 1991 Act of the UPOV convention.

Chart 3.4 shows that from 1971 - the year after the PVP Act was passed, to 2007, there was an increasing trend for the number of applications filed by both U.S. and foreign residents.

The steady and gradual growth in the number of plant patents and the application of PVP in the U.S. reflects the increased innovation in the field of agricultural biotechnology. Continuing high rates of innovation suggest that both of the patent system and PVP are working well in providing the protection to the inventors and plant breeders in the U.S.

Chart 3.5

Application for Plant Protection Under Plant Variety Protection Act (PVPA) and Plant Patent Act (PPA)

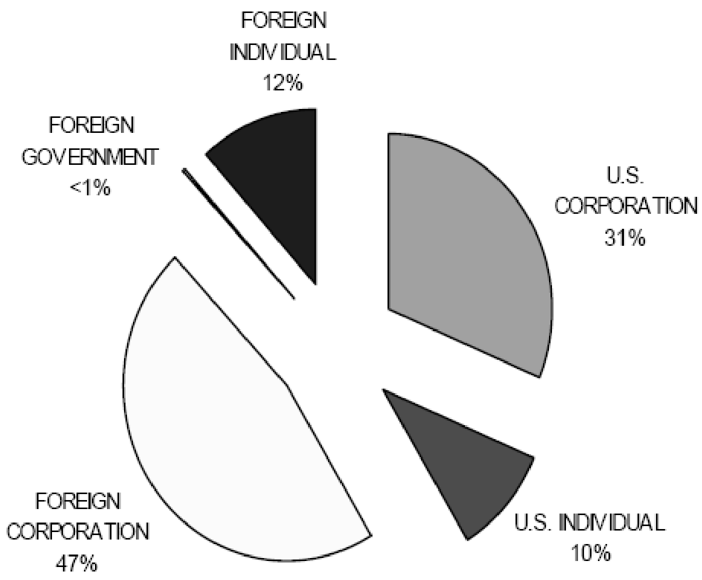


Source: USPTO

Chart 3.5 summarizes the number of applications under both PVPA and PPA, comparing the total number of applications by U.S. residents and foreign residents for a period of four consecutive years, from year 2002 till 2006. Clearly, the total number of applications for PVPA is less than those applications filed under PPA, but the trend as reflected from the chart suggested that PVPA remains relevant for some of breeders in the U.S.

Chart 3.6

Granted plant patents distributed by ownership category (2008)



Source: USPTO

Chart 3.6 shows the plant patent granted to U.S. residents which include U.S. corporations and individuals, as compared to foreign individuals, corporations and government. The majority of total ownership of granted plant patents, which is 60 percent, is held by foreign residents, while the remaining 40 percent is in the hands of U.S. residents. These facts appear to lead to the conclusion that the existence of three partially overlapping forms of protection for plant varieties and agricultural biotechnological inventions in the U.S. has managed to attract foreign companies and investors to seek for the best and most appropriate protection for their inventions. However, the low percentage of the ownership of plant patents by U.S. local companies and individuals would raise issues and concerns such as the marginalization of small farmers and breeders in competing with those large foreign corporations. At this juncture, developing countries like Malaysia should be cautious if it were to adopt the pro-patent attitude practised in the U.S., in order not to jeopardize the interest of small farmers and breeders.

3.3.5 How utility patents and PVP differ, and why one would be preferable

As an arm of the Department of Commerce, the USPTO is responsible for issuing both utility patents and plant patents to those agricultural biotechnological inventions which are novel, useful and non-obvious from the prior art. In contrast to utility patents and plant patents which are issued by the USPTO, a PVP Certificate is issued by the PVPO of the USDA Agricultural Marketing Service. Such certificates are granted on new, distinct, uniform and stable sexually propagated plants and tubers.

In many ways, the statutory scheme under the PVPA parallels the PPA. Nevertheless, the PVPA and the PPA differ significantly in their purposes, the scope and nature of their protection. The PPA grants a plant patent to one who 'invents or discovers and asexually reproduces any distinct and new variety of plant.'[402] The PVPA, however, entitles one to PVP if he has sexually reproduced the variety and otherwise met the requirements of the Act.[403] As a result, protection under the PVPA extends to the entire plant variety, while the PPA only protects that specific plant and its progeny.[404] This means that a PPA does not afford protection to a range of plants that would be similar to a plant described in the patent, but only to plants derived by asexual reproduction from the original plant that was the subject of the PPA application, while

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[402] 35 U.S.C. § 161 (2000).
[403] 7 U.S.C. § 2402 (2000).
[404] *Imazio Nursery, Inc. V. Dania Greenhouses*, 69 F.3d 1560, 1566-70 (Fed. Cir. 1995).

protection under the PVPA extends to any variety that is essentially derived from a protected variety, unless the protected variety is an essentially derived variety, to any variety that is not clearly distinguishable from a protected variety, and to any variety whose production requires the repeated use of a protected variety.

Due to the stringent requirements under general patent law, it is generally much more difficult to obtain a utility patent for plant than to obtain a plant patent or a PVPA Certificate. However, if an applicant can overcome these stringent requirements, a utility patent may be more desirable due to its greater scope of protection. In the wake of *Hibberd* (and even before), utility patenting of plant varieties has increasingly gained popularity. For economically important crops like corn and soybeans, breeders are making the obvious choice by choosing utility patent protection. As at July 2010, there were approximately 2000 corn (hybrid plus pure line), and about 1700 of soybean variety patents, plus smaller numbers of a range of other crops.[405] The reason for the popularity is evident: a greater scope of protection. Utility patents provide the broadest scope of protection to plants as they cover not only the plant, but plant parts in harvested or processed forms, methods of producing hybrid seed, as well as the hybrid seed and plants.[406]

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[405] Refer USPTO Patent Full-Text and Image Database, <http://www.uspto.gov/web/patents/classification/uspc800/sched800.htm#C800S320:001> (follow the red ―P‖ hyperlinks for ―320.1 Maize‖ and ―312 Soybean‖) [Accessed 12 July 2010].

[406] For example, US Patent No. 5,491,296, covering an inbred corn line developed by a breeder at Holden's Foundation Seeds, Inc., contains claims to a corn plant, pollen, ovules, tissue cultures, regenerated corn plants, hybrid corn seed developing suing this inbred as a parent, and methods for producing such hybrid corn seed; Refer USPTO Patent Full-Text and Image Database < http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2Fsearch-adv.htm&r=7&f=G&l=50&d=PALL&S1=5491296.UREF.&OS=ref/5491296&RS=REF/5491296> [Accessed 13 July 2010].

Unlike the PVPA, the Patent Act does not contain exemptions that limit the scope of protection. There are three important exemptions in the PVPA. First, the PVPA's provision safeguarding the 'public interest in wide usage' allows the United States Department of Agriculture to declare an otherwise protected variety open on the basis of equitable remuneration to the owner, upon a finding that no more than two years of compulsory licensing of a protected variety is necessary in order to insure an adequate supply of fibre, food, or feed and that the owner is unwilling or unable to meet public demand at a price which may reasonably be deemed fair. The PVPA's second exemption permits a farmer to save seed from protected varieties and to use such saved seed in the production of a crop without infringement. Third, the PVPA's 'research exemption' declares that the use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute infringement.[407]

The PVPA also limits the protection to a single variety, and the PPA limits the protection to a specific plant, that is an asexually propagated plant. The Patent Act has neither of these limitations. Specifically, the PVPA protection falls short of a utility patent because a breeder can use a plant that is protected by a PVP Certificate to develop a new inbred line, but the breeder cannot use a plant patented under the general Patent act for such purposes. With greater protection under the Patent Act, it is submitted that utility patent are the most valuable form of intellectual property, hence a patentee has a better option under patent protection to serve his or her commercial interests.

[407] 7 U.S.C. § 2544 (2000); Prior to 1994, farmer's exemption even allowed farmers to sell such saved seed to others without infringement.

Having said that, on first impression one may wonder what considerations could lead a plant breeder to choose the PVPA over the utility patent form of protection, particularly given the scope and flexibility of the protection available by a utility patent. It is interesting to note at this juncture that the PVPA offers certain advantages in comparison to the utility patent. It follows that despite the potential for broad protection for genetically engineered or otherwise improved plants by utility patents, the conventional plant breeder who discovers a distinctive new variety under cultivation or develops one by cross-breeding techniques is still free to use the PPA or PVPA to secure protection for the variety – and many have.[408] This is a clear indication that the availability of utility patents for plants has not discouraged the conventional plant breeder from seeking PPA or PVPA protection.[409]

One of the significant advantages of PVP is, unlike patent protection, applying for a PVP provides provisional protection. As soon as a PVP application is filed and the fee paid, the seed or plant variety may be marked 'Unauthorized Propagation Prohibited' or 'Unauthorized Seed Multiplication Prohibited'.[410]

Another benefit of PVPA protection for plant breeders is with regard to the novelty requirement. Under patent law, once a technology matures or

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[408] From 1971 to 1984, a total of 1297 PVPA Certificates were issued, while from 1985 to January 31, 1999, 2760 were issued. Source : Progress Report of the Plant Variety Protection Office, 1999, Refer: <http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Amicus_Briefs1/jembrief.pdf> [Accessed 09 April 2010].

[409] Some of the plant breeders are practically protecting their inbred plants under both the PVPA and by utility patents. One example is Pioneer Hi-Bred International Inc (in the case of *J.E.M. AG Supply, Inc. v Pioneer Hi-Bred Int'l, Inc* 534 U.S. 124 (2001)).

[410] 7 Code of Federal Regulations (C.F.R.) § 97.140 (2204) (regulations covering labelling are as follows: Upon filing an application for protection of a variety and payment of the prescribed fee, the owner, or his or her designee, may label the variety or containers of the seed of the variety or plants produced from such seed, substantially as follows: 'Unauthorized Propagation Prohibited – (Unauthorized Seed Multiplication Prohibited) – U.S. Variety Protection Applied For. Where applicable, 'PVPA 1994' or 'PVPA 1994-Unauthorized Sales for Reproductive Purposes Prohibited' may be added to the notice.)

becomes better known, novelty may be lost because the invention would be readily ascertainable from common knowledge. Therefore, once a biotechnological technique used in plant breeding loses novelty, the seed no longer will be patentable. PVPA protection would still be available on seeds that lack the novelty requirement because PVPA protection is available for new varieties that are new, distinct, uniform and stable.[411] Therefore, in such a scenario, plant breeders will be able to obtain PVPA protection on seeds that are not patentable.

Since both types of protection have value, some applicants choose to obtain both types of protection. For example, inbred lines to develop hybrids often get protected in PVPO. Such protection provides provisional protection when the PVP application is filed. Many inventors, however, may want to prevent exemptions for research and thus, would also seek patent protection.[412] After all, breeders can, and sometimes do, seek simultaneous PVP and UP protection for the same variety. While UP protection generally dominates PVP, PVP does specifically prohibit both importing and exporting a variety from the U.S.[413] while UP does not specifically prohibit exporting.[414] In this regard, it is submitted that such strength of combined protection could have anti-competitive effects by securing and strengthening the position of market leaders and limiting the entry of new competitors. It is thus not surprising that the seed industry in the U.S. is currently dominated by few dominant firms which control much of the seed supply.

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[411] 7 U.S.C. § 2483 (1994).

[412] WHITE, Katherine E., 2004. An Efficient Way to Improve Patent Quality for Plant Varieties. *NW. J. Tech & Intell. Prop.*, 3(1), pp. 84-85. Available at :<http://www.law.northwestern.edu/journal/njtip/v3/n1/5> [Accessed 08 March 2010].

[413] 7 U.S.C. § 2541(a)(2) (2006).

[414] 35 U.S.C. § 271(a) (2006).

In addition, there is a perception of cost effectiveness and reliability among plant breeders in the PVPA system that does not yet exist with regard to utility patents. Just as some industries are considered 'patent conscious', and others are not, some proprietary plant breeders are accustomed to the PVPA system and its procedures and limitations, and may simply be reluctant to change as a matter of practice and procedure.[415]

With regard to the differences between a plant patent and a utility patent, the former has at least two features that distinguish them from the latter. First, for plant patents, the requirement of 'distinctness' replaces the requirement for utility. The Fifth Circuit has defined distinctness as the 'aggregate of the plant's distinguishing characteristics, and the legislative history of the PPA provides a list of traits that may bear on it.'[416] Second, the requirement for an enabling disclosure is much attenuated for plant patents.[417] Relaxing the disclosure requirement was one of the chief reasons for adopting the PPA in the first place, for plant varieties were deemed incapable of precise verbal description for patent purposes. Besides, there may be a cost advantage, in certain circumstances, to proceed by way of plant patent rather than a utility patent. Plant patents may involve less attorney preparation and filing time and may avoid deposit costs.[418]

The differences of the three types of legal protection are aptly summarized in the Table 3.1 below.

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[415] SEAY, NICHOLAS J., *supra*, note 381, at 435.
[416] *Yoder Bros., Inc. v. California-Florida. Plant Corp.*, 537 F.2d 1347, 1378 (5th Cir. 1976).
[417] 35 U.S.C. § 162.
[418] *Ibid.*, at p. 434.

Table 3.1

The comparison of the UPA, the PPA and the PVPA

	Patent Law ('Utility' or Invention)	Plant Patent Law	Plant Variety Protection Law
Applicable to	Plant, plant part, gene, protein, method, etc.	Asexually propagated plant and its asexually propagated progeny.	Sexually (seed) propagated plant varieties
Rights to exclude others from	Making, using, selling, offering for sale and importing the plant, or any of its parts	Making, using, selling, offering for sale and importing the plant, or any of its parts	Selling, marketing, conditioning, stocking, offering for sale, reproducing, importing or exporting, using the variety to produce (as distinguished from develop) a hybrid or different variety
Term of Protection	20 years term from date of filing	20 years term from date of filing	20 years (25 years for trees or vines) from issuance of the certificate
Exemption	nil	nil	Crop Exemption: A person (farmer) may save seeds for planting on the person's land, but NO transfer to others for seed reproduction purposes

Generally, the UPA, PPA and PVPA can be viewed as presenting complementary, rather than conflicting, alternatives to protecting plants. If an applicant could satisfy the written description and claiming requirements of Section 112 of the UPA for his plant, he should be entitled to the broader protection afforded by the UPA; conversely, if he cannot satisfy those requirements, he should only be entitled to the narrower protection afforded by the PPA of PVPA. It is noteworthy that the standards for granting a plant utility patent are not notably different than for PVP, yet the scope of protection received is substantially greater. However, it is worth noting that, where a combined protection under both UPA & PVPA is granted, for example an inventor obtains rights under both UPA & PVPA for a new plant variety, conflict may arise with regards to the exceptions under the PVPA. Patent protection under the UPA would trump farmer's exemption under the PVPA, because such exemption neither exists nor recognized in the patent regime.

The flexibility of protection under the UPA is unparalleled by either PVPA or PPA. The fact that multiple claims can be drafted, unlike the PPA and PVPA, allows drafting of claims specifically targeted to cover all possible infringement, which include method claims of breeding or growing the protected variety. This is important because neither the PVPA nor the PPA reach this type of activity.

In short, the preceding discussion provides insights to support the conclusion that the three types of legal protection that is PPA, PVPA and UPA may co-exist in harmony, though conflict may also exist, in providing a strong IP protection for plants and agricultural biotechnological inventions. Nevertheless, the strengths of the UPA are manifest in terms of the broad and comprehensive protection. On this premise, UPA protection may well dominate the plant IP arena, although there will continue to be situations where the PPA and PVPA will be the preferred or only form of IP protection available.

3.4 Development of the legal protection for agricultural biotechnological inventions

In recent years, the USPTO has been criticized for granting patents with overly broad claims that grant a monopoly over property that is in the public domain, or patents for inventions that are not new and are obvious in light of the prior art. Although these mistakes are inevitable, such errors are more detrimental in areas where the patented subject matter is in naturally occurring substances, such as agricultural biotechnology, because one cannot design or invent around a plant.[419]

3.4.1 Case-law

The following discussion is focused on some important decided cases which ultimately shape the current laws in the U.S. vis-à-vis protection for agricultural biotechnological inventions. These cases are selected for the reasons that they are the landmark cases which played an important role in clarifying the legal issues revolving around IP protection for plants, in particular the three partially overlapping forms of protection for plants in the U.S.

(i)*Diamond v. Chakrabarty*[420]

In this case, the inventor sought to patent a genetically engineered bacterium whose function was to break down crude oil, a characteristic not inherently present in the bacteria. The Supreme Court stated that 'the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own….'[421]

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[419] WHITE, *supra*, note 412.
[420] 447 U.S. 303.
[421] *Diamond v. Chakrabarty*, 447 U.S. 303, at 310 U.S.P.Q. at 197.

In its extensively reasoned opinion, the Supreme Court explained that Congress plainly contemplated the notion that patent laws should be given wide scope and intended statutory subject matter to 'include anything under the sun that is made by man.'[422] The Court opined that the patent laws were intended to be construed broadly and that limitations on patents should be subject to the legislative process, not the judgment of the courts. According to the Supreme Court, *Chakrabarty's* microorganism was the result of human ingenuity and thus patentable: 'His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter – a product of human ingenuity having a distinctive name, character [and] use.'[423]

The Supreme Court also held that neither the PPA nor the PVPA were introduced to limit the field of application of the UPA. The Court explained that the purpose of these statutes was to remove several specific impediments to the protection of plants, most notably the idea that all plants, simply by virtue of being plants, are products of nature that fall outside the scope of patentable subject matter. The Court also explained that these statutes introduced a relaxation of the enabling requirements for plants. The Court added that the relevant distinction was not between 'living and inanimate thing, but between products of nature, whether living or not, and human-made inventions.'[424]

Nonetheless, it is to be noted that the question whether the *Chakrabarty's* holding opened the UPA for plant patents retained some lingering doubts. The

[422] *Ibid.,* at 309, 206 U.S.P.Q. at 197.
[423] *Ibid.,* at 309-10, 206 U.S.P.Q. at 197.
[424] *Ibid.,* at 313, 206 U.S.P.Q. at 199.

reasoning of the Supreme Court decision in *Chakrabarty* seemed to most practitioners, just as applicable to inventions in plants. After the decision in *Chakrabarty*, the USPTO began examining patent applications for inventions in plants, and practitioners began to consider the availability of such protection upon encountering developments in plant technology. Some USPTO examiners also interpreted *Chakrabarty* to permit utility patents on plants. The USPTO then began to resist issuing utility applications on plants, perhaps feeling that the propriety of permitting such applications should be ruled by an appropriate appellate body.[425] This uncertainty was eventually put to rest in 1985 by *Ex parte Hibberd*, which will be examined in the following discussion.

(ii) *Ex parte Hibberd*[426]

In *Hibberd,* taking its cue from the Supreme Court's expansive view of patentable subject matter endorsed in *Chakrabarty*, the USPTO in Board of Patent Appeals and Interference decision interpreted the subject matter of 35 U.S.C. § 101 to include plants. *Hibberd* contested the patentability under Section 101 of inventions claiming plant life. The Commissioner argued a variation on some of the arguments addressed by the Supreme Court in *Chakrabarty* regarding the proper interpretation of Section 101. The Commissioner's position in *Chakrabarty* was that since Congress specifically passed the PPA in 1930 and the PVPA in 1970 to provide patent-like protection for these specific types of plant life, it must have been Congress' understanding that living organisms were not patentable subject matter under Section 101. Hence, in *Ex parte Hibberd,* the Commissioner argued for a statutory construction asserting that because Section 101, the PPA, and PVPA

[425] SEAY, NICHOLAS J., *supra*, note 381.
[426] 227 U.S.P.Q. 443, WL71986 (1985).

must be construed together, and under the rule of statutory construction, specific statutes are found to prevail a general statute, hence the PPA and the PVPA must be the exclusive forms of protection for plant life covered by those Acts.[427]

It is to be noted that this argument was the basis of the USPTO's position prior to *Hibberd,* that utility patents were permitted only for hybrids and tuber-propagated plants because those plants could not be covered under the PPA or the PVPA. The Board of Appeals and Interferences rejected this argument in *Hibberd* and found no conflict between the statutes, hence adopting the position that plants may be protected by the UPA.[428] This position was formally adopted by the USPTO in a Notice from the Commissioner of Patents issued in October, 1985.[429] Amazingly, *Hibberd* continued as the primary precedent without court challenge from 1985 until *J.E.M. AG Supply, Inc. v Pioneer Hi-Bred* in 2001.

(iii) *J.E.M. AG Supply, Inc. v Pioneer Hi-Bred Int'l, Inc*[430]

Pioneer Hi-Bred International, Inc., the world's largest seed corn producer, holds seventeen utility patents issued under 35 U.S.C. Section 101 that covers the manufacture, use, sale, and offer for sale of its hybrid corn seed products. Pioneer sells its patented hybrid seeds under a limited label licence that allows only the production of grain and/or forage. J.E.M. AG Supply, Inc., doing business as Farm Advantage, Inc., bought patented seeds from Pioneer in

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[427] *Hibberd*, 227 U.S.P.Q. at 444.
[428] *Ibid.*
[429] Patent Office Notice, Plant Life – Patentable Subject Matter (Oct. 8, 1985), published in 2 COOPER, Iver P., 1982. *Biotehnology and the Law*, U.S.: Clark Boardman Callaghan, App. H3, at App.H-6.
[430] 534 U.S. 124 (2001); 122 S.Ct. 593 (2001).

bags bearing the license agreement and then resold the bags. Subsequently, Pioneer filed a patent infringement suit. In response, Farm Advantage filed a patent invalidity counterclaim, arguing that sexually reproducing plants, such as Pioneer's corn plants, are not patentable subject matter within section 101. Farm Advantage maintained that the Plant Patent Act of 1930 (PPA) and the Plant Variety Protection Act (PVPA) set forth the exclusive statutory means for protecting plant life.

The general issue of this case is whether sexually reproducing plants, more specifically hybrid[431] and inbred corn plants, are excluded from the scope of 35 U.S.C. § 101 and, accordingly, are not permissible subject matter for a utility patent. The Supreme Court in a 6-2 split, affirmed the decision of the Federal Circuit and held that utility applications for plants may be granted. The court further stated that plant patents and PVP are not the exclusive means of protecting new varieties of plants. This noteworthy decision has presumably increased the likelihood that more utility patents will be sought in the future.[432]

Clearly, the Supreme Court's decision runs parallel to policy considerations. Allowing inventors of plants to obtain a limited period of exclusivity in return for full disclosure is fully consonant with the overriding purpose of the patent laws. The public benefits when plant inventors provide the full disclosure required by a utility patent, in contrast to the limited disclosure provided by plant patents or PVPA certificates. No policy reason justifies discriminating against, and denying utility patent protection to, an inventor who can meet

[431] Hybrid corn plants are not 'varieties' since they lack the ability to be propagated unchanged.
[432] JANIS, MARK A., and KESAN, JAY P., 2002. U.S Plant Variety Protection: Sound and Fury...?. *Hous. L. Rev*. 3, p. 727.

the disclosure requirements of 35 U.S.C. § 112 merely because the invention is embodied in plant. Rather, in recent years, utility patent protection for plants has assisted progress in many areas of agricultural science.

Coming back to the case in issue, the parties did not dispute that both the PPA and the PVPA were enacted due to the difficulties encountered by plant breeders attempting to meet the written description requirement of 35 U.S.C. § 112(1) and to overcome the doctrine that 'products of nature' were not patentable subject matter under 35 U.S.C. § 101.[433] However, while the Petitioner (Farm Advantage) argued in this case that the legislative history of these two Acts evidenced that Congress intended to exclude plants from the ambit of Section 101, it is submitted that a better view is that, the Acts were intended to complement Section 101 protection, not to balkanize it by removing subject matter piecemeal from its scope.[434] The Supreme Court agreed with the Respondent (Pioneer), holding that neither the PPA nor the PVPA limits the scope of §101's coverage.

In its judgment, the Supreme Court observed that neither the PPA's original nor its recodified text indicates that its protection for asexually reproduced plants was intended to be exclusive. The 1930 PPA amended the general patent provision to protect only the asexual reproduction of a plant. And Congress' 1952 revision, which placed plant patents into a separate Chapter 15, was only a housekeeping measure that did not change the substantive rights or the relaxed requirements for such patents. Plant patents under the

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[433] Refer *Diamond v Chakrabarty*, 447 U.S. at 311-12, *Imazio Nursery, Inc. V. Dania Greenhouses*, 69 F.3d 1560, 1566-70 (Fed. Cir. 1995).
[434] This is the view of American Intellectual Property Law Association in its brief for Amicus Curiae in support of respondent supporting affirmance, Available at: < http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Amicus_Briefs1/jembrief.pdf > [Accessed 09 April 2010].

PPA thus continue to have very limited coverage and less stringent requirements than §101 utility patents. Importantly, Chapter 15 nowhere states that plant patents are the exclusive means of granting intellectual property protection to plants. The arguments that petitioners advanced for why the PPA should preclude assigning utility patents for plants were unpersuasive because petitioners fail to take into account of the forward-looking perspective of the utility patent statute and the reality of plant breeding in 1930.[435]

In *J.E.M. AG Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, the Supreme Court relied on *Ex parte Hibberd*, a 1985 USPTO decision that followed *Chakrabarty*. In *Ex parte Hibberd,* the USPTO held that plants were within the subject matter of Section 101. Thereafter, the USPTO has had a practice if giving utility patents to plants when a plant breeder shows that the plant he developed is new, useful and non-obvious. Using these requirements, the USPTO has issued over 1800 plant patents in 16 years.[436]

At this juncture, it is noteworthy the possible underlying reason of why the Court discussed the USPTO's decision to issue over 1800 patents is because of agribusiness in the U.S. Changing the USPTO system of giving utility patents to plants would inevitable cause enormous damage to investments made in the past 16 years. If the Court ruled in favour of the Farm Advantage, the Court would have to rescind more than 1800 seed patents which would affect the agribusiness and development in agricultural biotechnology.[437]

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[435] *Supra*, note 430.
[436] *Ibid*., 122 S.Ct. at 605.
[437] In the U.S., agribusiness is an entity that has hundreds of paid lobbyists in Congress and has put millions of dollars into the Democratic and Republican House and Senate campaigns.

As a matter of fact, the scope of subject matter relating to plants today that can meet the requirements of Section 112 far exceeds single plant varieties, as defined by either the PPA or the PVPA. The protection afforded by plant patents and PVP Certificates extends only to plant 'varieties'. This limited protection would not encompass the hybrid corn plants and seed covered by Pioneer's patents. And, while that protection may have met the need to protect new varieties invented or discovered through the 1970s, by the early 1990s agricultural biotechnologists could transform major field crops with genes preselected or mutated to add desired characteristics. The ability of plant scientists to alter and improve plants, therefore, had extended far beyond the creation of new varieties by conventional sexual cross breeding or asexual propagation.

In short, the U.S. Supreme Court in *Pioneer* laid to rest the question of whether sexually reproduced plants were statutory subject matter under Section 101. The Court made clear that if inventors of new varieties of plants are able to meet the stringent patentability standards of Section 101 and Section 112, they will be entitled to utility patent protection. Additionally, the Court clarified that Section 101 can also be reconciled with the PPA and the PVPA. The three statutes may provide overlapping protection and are not mutually exclusive. Thus, breeders of new plant varieties are free to apply for protection under each regime and may benefit from the protection provided by each regime.

(iv) ***Imazio Nursery, Inc. V. Dania Greenhouses***[438]

In this case, the owner of Imazio Nursery, Inc. (Imazio), was the inventor of the '336 patent which was entitled "Heather Named Erica Sunset." According to the '336 patent, Mr. Imazio discovered Erica Sunset heather in 1978 "as a seedling of unknown pollen parentage growing in a cultivated field of Erica persoluta, the variety believed to be the seed parent, where it was noticed because of its early blooming and particularly because of its reaching full bloom, from base to tip, more than a month before the parent plant begins to bloom." It was the early blooming of the Erica Sunset, during the Christmas and Valentine's Day seasons, that distinguished the Erica Sunset from other known varieties. Imazio sued Coastal for patent infringement alleging that Coastal's "Holiday Heather" infringed the '336 patent.

This case is important as it resolved a basic issue on what constitutes infringement of a plant patent. The U.S. Court of Appeals, Federal Circuit held that the scope of a plant patent is limited to the asexual progeny of a patented plant variety. The Court further held that 'variety' encompasses a single plant: the plant shown and described in the specification of the plant patent. Thus, in order for there to be infringement of a plant patent, the infringing plant must be an asexual reproduction of the plant claimed. In other words, infringement of a plant patent must involve a physical appropriation of asexually reproduced progeny of the patented variety. As such, independent creation is a defence to a charge of infringement of a plant patent.

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[438] 69 F.3d 1560, 36 USPQ 2d 1673 (Fed. Cir. 1995).

Interestingly, the case also provided guidelines as to scope of protection provided by the PVPA. The Court stated that 'asexual reproduction is the cornerstone of plant patent protection while sexual reproduction is the distinguishing feature of plant variety protection.' The court concluded that the scope of protection afforded as a result of sexual versus asexual reproduction must be different since with 'asexual reproduction the same plant is produced but in the case of sexual reproduction, a different plant, albeit like the parent plants, is produced.' This suggests that the protection provided by a PVP certificate is broader (at least in some respects) than that provided by plant patents.

This decision apparently clarifies the law in this area and restricts the scope of protection available for plant patents in the U.S. Nevertheless some authors[439] have criticized on the decision by the Court, reasoning that holders of U.S. plant patents will no longer have the same rights as those granted by utility and design patents, but rather a right more similar to copyright rights but administered through the USPTO. This is because *Imazio* stands for the proposition that to establish infringement of a plant patent it is necessary to prove that the accused plant is derived from, namley a copy of, the actual plant which prompted the filing of the application for plant patent.

In theory however, a plant patent owner could use genetic testing to prove the required copying under the *Imazio's* case standard. This may be easier said than done. First, a set of genetic markers that could be used to show derivation may not exist for the species at issue. Second, even if genetic

[439] One of them is Vincent G. Gioia; Refer GIOIA, VINCENT G., 1997. Plant Patents – R.I.P. *J. Pat. & Trademark Off. Soc'y*. 79, 516.

markers were available, they may not prove sufficiently variable to distinguish actual copying from mere genetic similarity. Third, obtaining such evidence and presenting it at trial will require a technical expert trained in genetic testing, further adding to the cost of litigation. Finally, if all of the foregoing can be achieved, it is still not a trivial exercise to obtain a jury verdict based solely on genetic evidence.[440] Having said that, in view of rapid developments in the field of biotechnology and genetic engineering, it will eventually be possible, though not easy, to furnish the required proof of infringement as decided in *Imazio's* case.

(v) *Yoder Bros., Inc. v. California-Florida. Plant Corp*.[441]

This case was a fight between two giants of the chrysanthemum business in the U.S., involving issues *inter alia*, relating to the plant patent law. The case was decided by 5th Circuit in 1976, but the principle and application of the PPA as demonstrated in this case still stands. In this case, Yoder Brothers (Yoder), plaintiff in the district court, sued, alleging infringement of twenty-one chrysanthemum plant patents by California-Florida Plant Corp. (CFPC) and California-Florida Plant Corp. of Florida (CFPCF) (sometimes referred to collectively as Cal-Florida). CFPC and CFPCF denied the infringement and filed antitrust counterclaims. As to seven of the chrysanthemum plant patents, the lower court directed verdicts for Yoder that the patents were valid and infringed and awarded treble damages.

[440] HANSON, R., and HIGHLAND, S., 2004. Protecting Plant Inventions. *In*: HOPKINS, A., and WANG, ZENG-YU, *Developments in Plant Breeding*. Netherlands: Springer. 2004, pp.381-395.
[441] 537 F.2d 1347, 1378 (5th Cir. 1976).

As far as the background of the case was concerned, chrysanthemums had been subject to intensive breeding efforts over the preceding thirty years;[442] each individual specimen was a genetically unique complex organism. New varieties of chrysanthemums were developed in two major ways; by sexual reproduction and by mutagenic techniques. Sexual reproduction, the result of self or cross pollination, produces a genetically unique seedling, the characteristics of which are impossible to predict. Mutagenic techniques simply accelerate the natural rate of mutation in the chrysanthemum plant itself. A central fact of life in the chrysanthemum industry is the ease with which cuttings can be taken from parent plants: from one chrysanthemum, it is theoretically possible to develop an infinitely large stock, by taking cuttings, maturing some into flowered plants, taking more cuttings, and so on.

Yoder started patenting some of its new varieties under the Plant Patent Act around the end of 1971, and in fact managed to secure plant patents on all new varieties it had introduced to the trade. Cal-Florida companies were the propagator-distributors, which built up mother stock from sources such as breeders, retail florists, or their existing flowers, and reproduced cuttings from that mother stock. In a sense, they were simply mass producers of cuttings. On the issue of patent infringement as alleged by Yoder, Cal-Florida companies asserted the invalidity of twenty-two U.S. plant patents.

In delivering its judgment, the Court interpreted and clarified the requirements of a plant patent, that is novelty, utility and obviousness. For plant patents, the requirement of distinctness replaced that of utility, and the additional requirement of asexual reproduction was introduced. The concept of novelty

[442] 30 years here refers to the year from which the case was decided that is in year 1976.

referred to novelty of conception, rather than novelty of use; no single prior art structure can exist in which all of the elements serve substantially the same function. As applied to plants, the Patent Office Board of Appeals held that a 'new' plant had to be one that literally had not existed before, rather than one that had existed in nature but was newly found, such as an exotic plant from a remote part of the earth.[443]

Interestingly, in defining 'distinctness', the Court made a reference to the legislative history of the Plant Patent Act, and accordingly observed that the characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; or soil conditions; colour of flower, leaf, fruit or stems; flavour; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form; and ease of asexual reproduction. Within any one of the above or other classes of characteristics the differences which would suffice to make the variety a distinct variety, will necessarily be differences of degree.

The Court was of the view that the third requirement, non-obviousness, was the hardest to apply to plants. Acknowledging the fact that in the case of plants, to develop or discover a new variety that retained the desirable qualities of the parent stock and added significant improvements, and to preserve the new specimen by asexual reproduction constituted no small feat, the Federal Circuit held that there was no meaningful way to apply the ordinary test of non-obviousness to plant patents, hence the statutory distinctness requirement was sufficient to satisfy the more general statutory requirements of patentability. The statutory criterion of distinctness was

[443] Supra, note 441, paras 149-152.

narrowly construed as applied both to patentability and to issues of infringement. In either context proof of a single significant distinguishing characteristic, whether taxonomic or functional, was sufficient to establish the existence of a distinct variety. The legislative history of the PPA indicated that in order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties, and it was immaterial whether in the judgment of the Patent Office the new characteristics were inferior or superior to those of existing varieties. [444] Experience had shown the absurdity of many views held as to the value of new varieties at the time of their creation.

It is noteworthy that the Court made it clear, for purposes of plant patent infringement, that the patentee must prove that the alleged infringing plant was an asexual reproduction, that it was the progeny of the patented plant. This is because, it is quite possible that infringement of a plant patent would occur only if stock obtained is used, given the extreme unlikelihood that any other plant could actually infringe. If the alleged infringer could somehow prove that he had developed the plant in question independently, then he would not be liable in damages or subject to an injunction for infringement. This example illustrates the extreme extent to which asexual reproduction is the heart of the plant patent system: the whole key to the 'invention' of a new plant is the discovery of new traits plus the foresight and appreciation to take the step of asexual reproduction.[445]

[444] *Ibid.,* paras 163-170.
[445] *Ibid.,* para 171.

This case was cited in the case of *Imazio*[446] (as discussed earlier). In fact, Cal-Florida was trying to persuade the Court on cross appeal, asserting that the absence of flowering plants grown from the cuttings it had admittedly taken from Yoder's patented plants was fatal to Yoder's infringement counts. This is because the patent claim in each instance described a mature flowering plant, and it was Cal-Florida's position that only another mature flowering plant could directly infringe. The Court ruled that the act of asexual reproduction was complete at the time the cutting was taken, hence it was not necessary to prove that the cuttings actually matured into flowered plants to show infringement. Under such a rule, it would be virtually impossible for a propagator-distributor directly to infringe a patent, despite the vital role he played in dissemination of plant material. In this regard, it is submitted that the protection afforded under PPA is very strong and comprehensive, covering any acts of reproducing asexually the plant or selling or using the plant so reproduced.

The Yoder case is significant in the sense that the requirements and effects of asexual reproduction as a prerequisite to plant patent protection have been recognized by the courts and the Patent Office. Although the case was decided in 1976, the principles relating to the implementation of PPA stand as good law until today. It is evident from the case that breeders and inventors from the horticultural industry have been benefitted from the strong protection offered under the plant patent system. After all, plant breeding is an expensive, complex procedure, which is eventually meant for the development of new varieties for consumers. The breeder must possess the skill and discrimination to spot potential new varieties and recognize whether they

[446] *Supra*, note 438.

possess desirable traits; facilities for elaborate testing and development must be available. Hence, the exclusive rights of the patent owners over their patented varieties are justifiable.

(vi) *Asgrow Seed Co. v. Winterboer*[447]

The Supreme Court in Asgrow's case resolved an ambiguity concerning what limit, if any, the PVPA placed on the quantity of saved seed one farmer might sell to another under the farmers' exemption. The farmers' exemption allows farmers (if they are not in the seed business themselves) to replant their fields with seed produced by plants grown in earlier years from protected seed.[448]

Petitioner, Asgrow Seed Company was the holder of PVPA certificates protecting two novel varieties of soybean seed, which it called A1937 and A2234. Respondents, Dennis and Becky Winterboer, were Iowa farmers. In addition to growing crops for sale as food and livestock feed, since 1987 the Winterboers had derived a sizable portion of their income from 'brown bag' sales of their crops to other farmers to use as seed. A brown bag sale occurs when a farmer purchases seed from a seed company, such as Asgrow, plants the seed in his own fields, harvests the crop, cleans it, and then sells the reproduced seed to other farmers (usually in nondescript brown bags) for them to plant as crop seed on their own farms. During 1990, the Winterboers planted 265 acres of A1937 and A2234, and sold the entire saleable crop to others for use as seed, at a lower price as compared to the price of varieties directly obtained from Asgrow.

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[447] 115 S. Ct. 788, 790 (1995).
[448] 7 U.S.C. § 2543.

Asgrow brought suit of infringement against the Winterboers in the Federal District Court for the Northern District of Iowa, seeking damages and a permanent injunction against sale of seed harvested from crops grown from A1937 and A2234. The Winterboers did not deny that Asgrow held valid certificates of protection covering A1937 and A2243, and that they had sold seed produced from those varieties for others to use as seed. Their defence rested upon the contention that their sales fell within the statutory exemption from infringement liability found in 7 U.S.C. § 2543. The District Court granted summary judgment in favour of Asgrow,[449] but it was later reversed by the U.S. Court of Appeals for the Federal Circuit.

Asgrow appealed, and the Supreme Court granted certiorari.[450] Justice Scalia, writing for the majority, reversed the Federal Circuit. The majority interpreted the PVPA as permitting the sale of seeds saved for purposed of replanting on the farmer's own acreage with the farmer's primary farming occupation being such that the sale of crops for reasons other than reproductive purposes constituted the preponderance of the farmer's business in the protected seed.[451] In short, the Supreme Court interpreted the PVPA's seed saving exemption so narrowly as to disallow many farmer-to-farmer 'brown bag' resales, viewing seeds as a licensed commodity. It is noteworthy that the Supreme Court justified its ruling as affording adequate encouragement for research and marketing and to yield for the public the benefits of new varieties. As far as small farmers and farmer's rights werere concerned, the case was viewed as an indicatiion of the trend of large businesses (the holder

[449] 795 F. Supp. 915 (1991).
[450] Shortly before the court rendered its decision, Congress amended the PVPA to bring it into line with the revised, 1991 UPOV Convention. Theses amendment narrowed the farmers' exemption even further, requiring farmers to secure the permission of the certificate holder before making any 'brown bag' sales. Refer § 2543 on 'Right to save seed; crop exemption'.
[451] *Supra*, note 438.

of a PVPA certificate, or even a utility patent) suing their small farm customers, that is the farmer as the end-user, rather than other large businesses or their market competitors.

3.4.1.1 The significance of the case-law in shaping the current position of laws on plant patents in the U.S.

Plants are perhaps the most thoroughly covered objects of IP protection in the U.S. The Supreme Court's decision in *Diamond v. Chakrabarty*[452] was instrumental in spurring the creation of a dynamic and flourishing biotech industry in the U.S. By finding that subject matter derived from nature is eligible for patenting if it is modified by man into something new, useful and unobvious, the Court provided assurance to biotech companies and their investors that emerging technologies were protected by the patent system even if they could not have been foreseen when the system was created 200 years earlier.

As far as agricultural biotechnology is concerned, since the Court's decision in 1980, the biotechnology industry in the U.S. has improved and saved lives around the world through increased crop yields. The U.S. biotechnology industry is a key component of its innovation economy, supporting more than 7.5 million jobs throughout the country and providing the US with a global competitive advantage.[453] The U.S. is presently the world leader in agricultural biotechnology, exporting roughly seventy-five percent of the world's bioengineered materials.[454]

[452] *Supra*, note 420.
[453] Refer : <http://www.bio.org/news/pressreleases/newsitem.asp?id=2010_0616_03> [Accessed 13 July 2010].
[454] JASEMINE, CHAMBERS, 2002. Patent eligibility of biotechnological inventions in the United States, Europe, and Japan: How much patent policy is public policy?. *The George Washington*

It is clear that in *Diamond v. Chakrabarty*,[455] the Supreme Court in effect laid the legal foundation that has contributed towards establishing the U.S. as the global biotech patent leader. While this case dealt specifically with a form of bacteria, the holding had significant implications for plant life. The Court's generous interpretation of the PPA and the passage of the PVPA established a new standard for invention that focused on 'natural' products and products of 'human effort. In this regard, it is noteworthy that *Diamond v. Chakrabarty*[456] has opened the floodgates for broader definitions of what is patentable. The decision, in addition to accommodating the high-tech direction of agricultural R&D, provided fairly strong patent protection for important aspects of agricultural inventions.

With this foundation in place, *Ex Parte Hibberd*[457] helped to clarify the actual stand on patenting of transgenic plants. *Hibberd*, which dealt with patenting of maize plant technologies that included seeds, allowed plant patents to be included under the broad category of utility patents. Utility patents are preferred by plant breeders because they allow patenting of the individual components of varieties. After *Hibberd*, the PTO granted over 1800 expansive utility patents for germplasm.

In 2001, the Court again expanded the definition of what is patentable, which in effect diluted the PPA and PVPA exemptions. In *J.E.M. AG Supply v. Pioneer*

International Review.[online] Available at : <http://www.allbusiness.com/legal/intellectual-property-patent/915888-1.html> [Accessed 13 July 2010].
[455] *Supra*, note 420.
[456] *Supra*, note 420.
[457] *Supra*, note 426.

Hi-Bred International,[458] Pioneer Hi-Bred, a large seed company, sued a small Iowa seed supply company, Farm Advantage, for violating patents on hybrid corn seed. Justice Thomas, writing for the majority, concluded that newly developed plant breeds are covered by expansive utility patents and that neither the PPA nor the PVPA can limit the scope of a utility patent. The majority's broad interpretation of the legislation reinforced the position of seed patent holders and transgenic plant inventors. The Supreme Court thus opened the door for widespread use of utility patent protection for protecting potentially any economically important plant variety.

Cases such as *Yoder Bros.*[459] and *Asgrow Seed*[460] are significant in the sense that they serve to clarify the interpretation of the patent laws and PVPA. These cases are essentially indicative and good markers of the U.S. courts' approach in ensuring the continuous, concerted effort of protecting inventors and plant breeders' investment in the development of plant varieties.

3.4.2 Some controversies over plant patents in the U.S.

The protection afforded by the general patent statutes creates incentives for inventors and companies to research and develop new products to benefit mankind by allowing them to make a profit in the twenty year period allowed for inventors to market their invention free from competition.[461] Although patent laws are responsible for providing scientists and inventors with incentives to produce new products, the use of biotechnology in agriculture spawns debate because of the potential effects on farmers. Scholars worry

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458 *Supra*, note 430.
459 *Supra*, note 440.
460 *Supra*, note 446.
461 35 U.S.C. § 101 (1994).

that intellectual property laws would allow large corporations to profit from agricultural biotechnology (agribiotech) at the expense of farmers. Farmers fear that allowing agribiotech companies patent protection will force the agriculturists to pay royalties for the purchase of genetically altered plants. This obligation to pay royalties and increased costs likely will reduce the annual net profits of farmers. Farmers even fear that the increased costs of seed coupled with low crop prices will drive many of them out of business.[462]

Legal challenges stem from licensing agreements and intellectual property protection that accompany patented seeds. These licensing agreements from agribiotech companies are feared to lead to the 'industrialization' of farming by requiring farmers to use limited licences with seed purchases and to encourage the use of contract production.[463] For example, Monsanto[464] does not simply sell seed to farmers, it also requires farmers to buy licences to use the company's seed technology. To use Monsanto's Roundup Ready soy beans, the farmer must agree to use the seed only once. Another example is Pioneer's[465] practice of placing tags on its bags of corn that limits the farmer to planting the seed for only one year. Such licences often forbid the farmer from the traditional practice of saving seed to replant the following year. This licence contradicts farmers' traditional practice of saving seed from one year to re-plant the next year and increase their operating costs. Many farmers claim they cannot afford to purchase more expensive bioengineered seed each

[462] NILLES, ANDREW F., 2000. Plant Patent Law: The Federal Circuit Sows the Seed to Allow Agriculture to Grow *Land & Water L. Rev*. 35, pp. 355-373, at p.361.

[463] HAMILTON, NEIL D., 1997. Reaping What We Have Sown: Public Policy Consequences of Agricultural Industrialization And The Legal Implications Of A Changing Production System, *Drake L. Rev*. 45, 289-310, at p.295.

[464] Monsanto is an agribiotech company engaged in the manufacturing and selling agricultural products including herbicides. It is also engaged in biotech R&D of crops. Refer : <http:// http://www.monsanto.com/>.

[465] Pioneer is an agribiotech company that produces genetically engineered crops and is the world's largest seed corn producer. Refer *Pioneer Hi_Bred Int'l Inc., v. J.E.M. Ag Supply Inc.,* 49 U.SD.P.Q. 2d 1813.

year. On the contrary, agribiotech companies claim the licences are necessary to protect their investments in R&D[466] and have instituted lawsuits against farmers who saved seed for future planting.[467]

Contracts placing specific restrictions on farmers' ability to save seed have engendered significant controversy. Farmers' demanded that there should be a balance between the farmers' traditional right to save seed with the cost required to develop improved varieties through genetic engineering. At the same time, there are always compelling arguments from patent owners for preserving incentives to develop improved varieties to benefit farmers.

The current patent laws in the U.S. give unquestionable right to agribiotech companies to patent plants. As discussed in the preceding part of this chapter, the issue of whether plants are patentable under the general patent statutes was decided by the U.S. Court of Appeals for the Federal Circuit. In *J.E.M. Ag Supply, Inc*. v *Pioneer Hi-Bred International*, it was held that seeds and seed-grown plants are patentable subject matter under the general patent statutes.[468] Some commentators were of the opinion that the Supreme Court majority's decision in *Pioneer'*s case prohibits farmers from saving seed for the following year's crop and thus erodes the farmer's right to save seeds for the benefit of society, an act which is permitted via exemptions in the PVPA. The dissenting opinion in Pioneer remarked that a grant of utility patents to plants would destroy the two important exemptions under the PVPA; first, that a farmer would not face patent infringement if he saved the seeds and planted them in future years, and second, that the PVPA permitted the use and

[466] HAMILTON, *supra* note 463.
[467] NILLES, *supra* note 462.
[468] HAMILTON, *op.cit.*

reproduction of a protected variety for plant breeding or other bona fide research.

Until and unless the Congress makes an amendment to the UPA – by carving out an exception that PVPA to be the exclusive means of protection of new plant varieties and that farmers have the right to save seed,[469] the current law in force at present is that plant and plant varieties which include seeds are eligible to be protected under the UPA. Allowing plant patents will continue to allow plant breeders to develop newer and better varieties of crops, which eventually increase crop yields, reduce the need for pesticide use, and promote no-till farming, all of which benefit the farmer economically.[470]

3.4.3 Recent development in plant bioscience and possible effects on the U.S. current laws on plant-related inventions

Modern biotechnology allows plant breeders to select genes that produce beneficial traits and move them from one organism to another. Plant biotechnology is far more precise and selective than crossbreeding in producing desired agronomic traits. Farmers throughout the world spend an estimated USD36 billion a year to buy seeds for crops, especially those with sought after traits such as hardiness and pest-resistance.[471] They are unable to grow these seeds themselves because the very act of sexual reproduction

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[469] All that is needed to overturn the majority's opinion in the Supreme Court decision is one sentence added to the PVPA. This sentence would simply affirm that the PVPA is intended by Congress to be the sole manner of gaining intellectual property rights over seeds. Rodney Nelson of Nelson Farm Enterprise suggested this addition to the statutes in a letter to North Dakota Senators Dorgan and Conrad and Rep. Pomeroy, Refer : <http://www.cropchoice.com/leadstrya594.html?recid=540> [Accessed 12 April 2010].

[470] For example, in a 1997 survey of the corn belt, *Bt.* corn users produced an average of 13.5 more bushels of corn more per acre than non-*Bt* corn users. Also, Roundup Ready soybeans cost twelve dollars less per acre for weed control and lead to 4.5 more bushels of soybeans per acre. Refer NILLES, *supra* note 389, pp. 370-371. *Bt* corn is a variant of maize, genetically altered by methods of to express the bacterial *Bt (Bacillus thuringiensis*) toxin, which is poisonous to insect pests. The corn is genetically engineered to provide protection against the European corn borer. Refer US Department of Agriculture < http://www.ers.usda.gov/briefing/biotechnology/glossary.htm> [Accessed 01 December 2010]

[471] ANON., 2010. Asexual Plant Reproduction May Seed New Approach for Agriculture. *Science Daily* [online], Available at: < http://www.sciencedaily.com/releases/2010/03/100308132035.htm> [Accessed 20 July 2010]

erases many of those carefully selected traits. So year after year, farmers must purchase new supplies of specially-produced seeds. Sexual reproduction in plants involves the generation of male and female gametes that each carry half of the organism's genes. Flowering plants exhibit the most advanced form of sexual plant reproduction, producing pollen-derived sperm cells that join with egg cells to produce seeds. Each seed, then, is genetically unique. There are several types of asexual reproduction in plants, but all produce the same result: genetically identical daughter plants.

It is worth noting the latest development in plant bioscience and biotechnology, which has reported a success and indeed a breakthrough. This happened recently when a group of scientists were reported to have moved a step closer to turning sexually-reproducing plants into asexual reproducers. Vielle-Calzada, a plant researcher at the Center for Research and Advanced Studies of the National Polytechnic Institute in Irapuato, Mexico, together with his colleagues, have been working and studying on a specific type of plant named *'Arabidopsis thaliana',* a small flowering mustard plant with a compact and well understood genome and which does not reproduce asexually. These scientists have managed to show that silencing a protein called *'Argonaute 9'* causes the plant to begin reproducing asexually instead.[472] In other words, in the process, the plant was able to produce a clone of itself asexually. The finding is significant as it could have profound implications for agriculture and would eventually affect the current system of IP protection in the U.S. and worldwide. From farmers' and breeders' perspective, such a finding would allow them to simplify the labor-intensive cross-hybridization methods they now use to produce hearty seeds with desirable traits.

[472] *Ibid*.

From the legal aspect, if in the future all sexually propagated plants could be propagated asexually, it would diminish the role and value of PVPA, which is meant for the protection of sexually propagated plants. Nevertheless, the finding is still at the infancy stage and there are lots of stages and thousands of laboratory experiments to be done by those researchers towards creating a fully asexual *Arabidopsis* plant. This is because the current mutants do not develop completely asexual seeds. But by highlighting the infant success in plant reproduction, those scientists have actually moved a step closer to a slew of agricultural possibilities. They are now focusing on the ways and methods to discover and to trigger the second and final step of making sexual plants asexual.[473] With that in mind, the UPA seems to be in a better position and would stand in the list of preference by breeders and inventors as it offers the broadest level of protection provided the patentability requirements are met.

3.5 Comparison of the U.S. and European approaches

Other industrialized countries have been slower than the U.S. to grant patent protection on living organisms which include transgenic plants and new plant varieties. A breakthrough occurred in 1999,[474] when the EPO began to grant patents on genetically engineered cops. A comparison between the European and the U.S. contexts shows that there are striking similarities and differences between the European and the U.S. approaches to the establishment of protection for plants under the general Patents Acts. Initially, under the first-generation Patent Acts, the European and the U.S. framework ran parallel. The

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[473] *Ibid.*
[474] *Novartis*' case, *supra*, note 266.

language of the first-generation patents acts[475] was equally unclear in both the U.S. and Europe with respect to the patentability of plants. Equally similar were the first-generation objections raised to deny patent protection to plants in Europe and in the U.S. [476]

Subsequently, the perception that general patent law was inappropriate for the protection of plants resulted in the establishment of plant-tailored protection systems in both Europe and the U.S. The divergence between European and American approaches occurred with the enactment of the second-generation Patent Acts. The EPC and its member states adopted an explicit exclusionary provision regarding plant varieties, while the 1952 U.S. Patent Act contained no similar clause – but neither did U.S. patent law contain a provision that explicitly allowed the patentability of plants.

The chasm between European and American patent law which was created with the inception of the EPC was quickly bridged. General discontent over inadequate plant protection systems and the confusion regarding the status of the law led to a resurgence of demand for plant protection under general patent acts in both Europe and the U.S. The gap between the European and the U.S. plant-patent policies reopened in 1995 when the EPO decided, in *Plant Genetic Systems (PGS)* case, to cease granting patent claims on plant *per se,* and this gap remains open as result of the affirmation of the PGS decision in *Novartis* case. As a result, the question whether plants may be

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[475] In the U.S., first-generation patent acts refer to first U.S. Patent Act of 1790, which was later on replaced three years later. The revision to the Act was made in 1836 and 1870. First-generation patent acts in Europe denote various national patent acts in continental Europe which were established starting around the middle of the 19th century such as the Belgian Patent Act of 1854 and the German Patent Act of 1877.
[476] OVERWALLE, *supra* Note 346.

protected under the general patent act must now be answered differently in the U.S. than in Europe.[477]

The difference between these two jurisdictions can also be seen in terms of application and scope of the research exemption which is generally available under patent laws. Most national patent laws permit third parties to engage in experimentation or research related to the patented invention. As far as the U.S. patent laws are concerned, there is no explicit research exemption in the Patent Act of 1952, but judicial decisions have allowed the 'experimental use' of a patented invention as a defence to an allegation of infringement. Despite its value in meeting the goals of the patent regime, the experimental use exception has been interpreted by the Federal Circuit in 2002[478] in a manner that has significantly narrowed its scope and rendered its availability uncertain. The decision in effect has substantially eliminated the experimental use defense to patent infringement, especially where university-industry collaborative research is concerned. At present, most organizations carrying out research or experimental work involving patented inventions in the U.S. could find themselves liable for patent infringement. Notably, there have been no reported decisions wherein the experimental use exceptions has been considered specifically in the context of plant biotechnology. Nevertheless, the experimental use defense is submitted to remain relevant to the discussion of plant biotechnology and research initiatives related to agriculture in developing countries like Malaysia.

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[477] *Ibid.*

[478] In the case of *Madey v Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), it was held that '…regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act as in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profits status of the user is not determinative.'

The approach in Europe is somewhat different compared to the American approach. Member States in Europe have adopted research exemptions, inspired by Article 27(b) of the Community Patent Convention (1989 version),[479] and whose scope is generally broader than that of the American one. The experimental use exception in the UK is enshrined in section 60(5) of the Patents Act 1977 which says that: 'An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –(a) it is done privately and for purposes which are not commercial; (b) it is done for experimental purposes relating to the subject-matter of the invention.' However, judicial interpretation of the experimental use exception in the UK has been relatively scarce. Indeed, in Europe at large and especially in relation to the intersection of biotechnology and the experimental use exception, case law is exceedingly sparse. While some guidance may be extracted from the new judgments which have been delivered in the UK, it is all too easy to limit their precedential value to the specific facts and patented technologies which gave rise to the dispute in question.[480]

In the U.S., the debate on patent protection for plants was settled when the courts filled the legal vacuum created under the pre-1952 patent acts (and prolonged by the 1952 Patent Act) in favour of UPA. In Europe the discussion is probably not over, and the picture is still obscure. On the one hand there is current EPO case law, according to which plant varieties are non-patentable

[479] Refer : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:41989A0695(01):EN:HTML> [Accessed 26 July 2010]

[480] For example, in the case of *Monsanto Co. v Stauffer Chemical Co. and another* [1985] RPC 515 (CA), the Court of Appeal interpreted Section 60(5)(b) as was not so broad to encompass trials conducted by third parties and on lands other than the defendant's premises.

subject matter, while on the other hand there is the Biotechnology Directive of the European Parliament and of the Council which allows patents for plants, but denies patents for plant varieties. At this juncture, it is to be noted that some legal jurists[481] in the area of plant biotechnology have been proposing the EPO to accept the fact that patent protection for plants can be justified from a legal point of view, and perhaps rescind Article53(b) of the EPC. The suggestion was made with the aim of paving the way for plants to be covered by patents and removing any ambiguities and uncertainties on the issue of patent protection for plants (which includes plant varieties), hence realigning the Europe's position with the U.S. in the area patent protection for plants.

3.6 How relevant is the U.S. system to Malaysian IP laws on agricultural biotechnological inventions

The patent laws of developed nations such as the U.S. are noted for providing the broadest protection for biotechnological inventions. Today, in the U.S., utility patents have been issued on both field crops, such as corns, soybeans and cotton, and vegetables, such as tomatoes and squash, having properties enhanced by both conventional breeding techniques and by direct gene transfer. This patenting activity has not deterred farmers from adopting this new technology. The U.S. farmers plant more than 70% of the biotech crops grown globally. For example, in 2000, about 61% of all cotton and about 54% of all soybeans planted in the U.S. were transgenic. As a matter of fact, these crops are no longer laboratory curiosities, they are now in the field. Many U.S. farmers who grow genetically modified (GM) crops are realizing substantial economic and environmental benefits, such as lower production costs, fewer pest problems, reduced use of pesticides, and better yields, compared with

[481] One of them is Geertrui Van Overwalle, *supra* Note 304.

conventional crops.[482] In comparison in Malaysia, the scenario is very much different. Although significant progress is being made in developing GM crops such as rice, papaya, pomelo, orchid, pineapple, oil palm, chili, rubber, and so forth, there is still no commercial release of GM crops, but they are all confined to field trials.[483] It would take at least a couple of years before these GM crops could be released commercially, due to the heightened awareness and concern over the effects of GM crops among Malaysians in particular and in developing countries in general.

With regard to the IP laws on protecting the agricultural biotechnological inventions, apparently there is no other country offers so many opportunities for IP coverage of plants; the current state of the law in the U.S. offers opportunities for plural regimes of protection as utility patents, PPA and PVPA and these cover any particular plant. It may be patentable under the PPA if it is asexually reproduced; it may be patentable under the general utility patent statute if it is new, useful and non-obvious; and it may be eligible for PVPA protection if it is new, distinct, stable and uniform plant. In this position, the U.S. system is truly unique in the world as no one else offers such an expansive opportunity for plant protection. In fact, the U.S. leads the global strengthening of IP protection, and has been the leader in development and commercialization of biotechnology in agriculture in the form of transgenic crops. Countries that invest little in research and development obtain a temporary advantage by limiting patent protection and free riding on the research investments of the more developed countries. The scope of patent

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[482] This has been reported by the US National Research Council. Refer : <http://www.finfacts.ie/irishfinancenews/article_1019470.shtml> [Accessed 22 April 2010]
[483] The fact is confirmed by MARDI during the semi-structured interview carried out in mid 2008 for this thesis research purposes. Also refer to : <http://www.agbioforum.org/v7n12/v7n12a01-hautea.htm> [Accessed 22 April 2010]

eligible subject matter typically expands as a nation realizes increasing economic growth and industrialization, and this is to some extent is very true for a developing country like Malaysia. As far as Malaysian IPRs system is concerned, patents are currently not available for plant varieties.[484] Hence, the Malaysian Protection of New Plant Varieties Act 2004 was introduced with the aim of giving adequate protection to breeders of new plant varieties. There is no court decision on whether a transgenic plant (which may embrace plant varieties) could be protected under the Patents Act 1983, but it is submitted that the answer is in affirmative, as the exception from patentability is only meant for plant varieties.

Innovations in agricultural biotechnology in the U.S. have evolved greatly. The important role of the publicly funded institutions in R&D biotech is now in the hands a few privately funded firms, and has clustered around a few key crops, such as soybean, cotton, maize and canola, while ignoring other 'orphan' crops. Developed countries like the U.S. have moved towards complex, modern biotechnology, relying on private funding and increased patenting, whereas developing countries like Malaysia, are still depending on public funding and conventional breeding. As far as the Malaysian situation is concerned, the Government and other public bodies continue to be the primary sources of R&D funding, providing financial support to an overwhelming proportion of their R&D activities. Thus, the R&D models of the U.S. as the leader in biotechnology and a developed country, and Malaysia as a developing country fundamentally differ.

[484] Section 13(b) Malaysian Patents Act 1983.

In developing countries like Malaysia, the right of farmers to save, exchange and save seeds, and sell their harvest is a matter of high importance, as well as preserving and ensuring the continuation of traditional farming practices, side by side with the development of modern agricultural biotechnology. Whereas in the U.S, in spite of some controversies over plant patents and the limited right of farmers to save seed, the greater influence and lobbying from nursery owners and large biotech companies is actually contributing to the current system and IP laws in the U.S.

Among developing countries, there has been a deep suspicion about IP protection. Most view it as colonialism by developed countries. Genetic engineering, along with the extension of IP protection to plants, has led to the acquisition of most of the world's seed production capacity by a small number of mega life science companies.[485] Although Malaysia aspires towards the transformation into a highly industrialized nation by 2020, the different scenario in terms of much slower progress of its R&D biotech, and different nature of farming industries eventually shape the most suitable IP laws and legal system. Although the national legislation such as the Malaysian Patents Act 1983 is in need of some revision and amendment to keep pace with the latest biotechnological advancements, the paramount consideration is given to protect the interest of small and medium sized local farmers, as well as local biotech companies, and to ensure that the R&D outputs generated by the public funded institutions benefit the local breeders and farmers ultimately.

[485] J.P.KESAN, 2007. Seeds of Change: A Link among the Legal, Economic and Agricultural Biotechnology Communities. *In*: J.P. KESAN, ed. *Agricultural Biotechnology and Intellectual Property: Seeds of Change*. Oxfordshire: CAB International, p. xxi.

3.7 Conclusion & Contribution

The property right of agricultural biotechnological inventions is a topic of much debate. Scholars and policymakers debate the pros and cons of different property regimes that protect plant innovation. The need to protect against unauthorized use of plants arises not only from the inherent value of the plants, but also because they are so easily misappropriated. Once a plant is sold, it can be reproduced essentially in perpetuity, each time producing an identical copy of the original plant, in particular those plants which can be reproduced asexually. According to the literature, the effective protection of property rights offers adequate incentives for R&D in a biotechnology market controlled by private firms. When it comes to contemporary patent protection for new plants and other living things, it is important to note that in the U.S., two important statutory changes provide, as has been discussed throughout this chapter. One took place in 1930, and the other in 1970. In both instances, Congress responded to what industry players said was an inability to get utility patent protection for their inventions on an equal footing with other industries. Congress expanded the scope of patentable subject matter on both occasions.

As far as the American situation is concerned, the growth of private research is parallel with the consolidation of the private sector in multinational corporations, gradually replacing the significant role of governmental research institutions in biotechnology. On the contrary, developing countries such as Malaysia are still relying on government funded institutions to carry out most of the R&D in biotechnology. The difference in approach is understandably due to the different levels of commercial agricultural development leading to different political considerations in the development of their respective intellectual property rights.

It is submitted that the current system as being practised in the U.S. (namely the three-tier protection for plant innovation) would not totally fit the situation in Malaysia. In other words, the U.S. system is not the ideal model for a developing country like Malaysia, hence there is no way that Malaysia could adopt the American approach wholly. Nevertheless, the patent system as being practised in the U.S. would to some extent serves as a good guidance and hence would be relevant to Malaysia in some ways. For example, it has been shown from the charts and statistics in the preceding discussion, that the PVP system which offers much simpler procedure and lower fees essentially remains relevant among small and medium size companies in the U.S., while the PPA is much more popular among foreign applicants, dominating a substantial percentage of plant patent applications and patent grants. In a developing country like Malaysia wherein small and medium size farming communities constitute an important segment of the industry, it is submitted that the alternative, simpler system as available under the new statute (PNPVA) would gradually gain popularity among local breeders, though the effectiveness of the protection remains to be seen, vis-à-vis its exceptions and relatively generous exemptions.

Based on the U.S. experience as well, there is also very high probability that if Malaysia were to strengthen its current patent laws, for example, by lifting the ban on patenting plant varieties, multi-national corporations and big international players would be the ones in the front row to file their patent applications, rather than the small farmers of local RIs.

The current Malaysian Patents Act 1983 expressly excludes plant varieties from patentability; until and unless the provision of the Act is amended, it remains to be seen whether there is a real need for lifting the ban in the near future, in view of the recent implementation of the Malaysian Protection of New Plant Varieties Act 2004 (PNPVA). The fact that patent protection, other than the plant itself, would cover processes and compositions important in the development of transgenic plants, such as regeneration and transformation methods, genes for insect, herbicide, and disease resistance, and vectors and promoters for the expression of such genes in plants, is leading to inevitable submission that in order for Malaysia to boost the growth of its agricultural biotechnology industry, a strong protection under patent laws is necessary to assure extensive protection for inventors in plant biotechnology. After all, such new varieties of plants take decades and often constitute the major portion of a biotechnology company's competitive advantage.

Chapter 4

Malaysian Agricultural Biotechnology: An Outlook on Recent Developments, Regulatory Framework and Impediments

4.1 Introduction

Biotechnology has been internationally acknowledged as the scientific and technological revolution of the 21st century. As far as Malaysia is concerned, biotechnology is set to be a major contributor to its economic growth. Although it is still in its infancy stage, its potential is enormous. With the nation's rich biodiversity, cost-competitive labour and strong agricultural base, Malaysia stands to gain from its biotechnological development that will position the country as a key global player by 2020. The country aims to gain a slice of the lucrative global biotechnology market. In fact, it is ready to learn from and emulate the best biotechnology research and development (R&D) and industry practices and has set its sights on doubling the number of its biotechnology and biotechnology-related companies to 400 by 2010. The target was plausible as based on the Malaysian Biotech Corp Country Report 2009/2010[486], as at 30 September 2009, a total number of 349 biotechnology companies were identified in Malaysia, a three-fold increase from 117 companies in 2005.

Malaysia stands as the 4th mega-diversity nation in Asia and 12th in the world, and is blessed with rich natural resources such as the world's oldest rainforest, an estimated 12,500 flowering plants species and more than 100,000 animal

[486] The report is available at : <
http://www.biotechcorp.com.my/Documents/AboutBiotechCorp/country%20report%20double.pdf
> [Accessed 01 December 2010]

species.[487] With this uniqueness, the country realizes its biotechnology potential, hence aims to set itself apart from its Asian neighbours and rivals. As far as Malaysia is concerned, the niche area is primarily agricultural biotechnology, other than healthcare biotechnology and industrial biotechnology.[488] The country's global biotechnology competitiveness is shown in the chart below:

Table 4.1

Malaysia's Global Biotechnology Competitiveness as at 2006

	Malaysia	Singapore	South Korea	China	India	New Zealand	Australia
Strengths	Biodiversity Low Cost	International talent Dedicated foster agency	Investment Biomaterials	Human Capital Low Cost	Human Capital Low Cost	Research & Commercialisation Services	Research Infrastructure IP Protection
No. of Biotechnology Companies	27	25	41	250	250	44	226
No. of Research Institutions	14	6	103	222	37	28	94
National Biotechnology Plan	Yes	Yes	Yes	No	No	Yes	Yes
No.of R&D Researchers	3,400	16,700	136,300	742,700	149,300	8,200	65,800
World Ranking on Patent Protection	33	7	37	39	47	15	5
Activities	Genomics Pharmaceuticals Molecular Biodiesel Nutraceuticals Agriculture	Genomics Bioengineering Bioprocessing Bioinformatics Nanotechnology	Biomedicine Bioagriculture Biofood Biohealth Marine	Agriculture Biomedicine Bioresources	Bioinformatics Therapeutics Industrial Vaccines	Biomedicine Food Tech Plant Science Environmental Biosecurity Agrotechnology	Pharmaceuticals Biomedicine Genomics Therapeutics Bioengineering Nanotechnology

Source: Ernst and Young[489]

[487] THE MALAYSIAN MINISTRY OF SCIENCE, TECHNOLOGY AND THE ENVIRONMENT, 1998. *First National Report To The Conference Of The Parties Of The Convention On Biological Diversity*, Available at:< http://www.cbd.int/doc/world/my/my-nr-01-en.pdf> [Accessed 01 December 2010]
[488] Refer <http://www.biotechcorp.com.my/rakyat.html> [Accessed 20 January 2009]
[489] Biotech Corp Annual Report 2007, p.4, Available at: < http://www.biotechcorp.com.my/pdf/anual_report_9608.pdf> [Accessed 21 January 2009]

This chapter examines the growth and development of Malaysia's biotechnological sector, focusing on agricultural biotechnology. In this regard, the chapter will essentially cover the discussion on the Malaysian National Biotechnology Policy (NBP), the legal and regulatory framework affecting agricultural biotechnology in Malaysia, the impediments encountered by the industry to the success of biotechnological R&D, as well as the role of the agencies and companies in Malaysia which are involved in agricultural biotechnology. A critical look at and a detailed discussion of the role of the local agencies and companies that contribute to the growth and development of agricultural biotechnology is crucial as they would be one of the determining factors to the success of the industry in Malaysia.

4.2 The National Biotechnology Policy

Biotechnology was identified as a key technology that could drive and support the nation to evolve into a knowledge-based economy. Hence, the Malaysian Government in its Ninth Malaysian Plan (2006-2010) is making a concerted effort to create an environment that is conducive to innovation and investment in biotechnology. During the Plan period, the emphasis is on building the capacity and capability of human resources as well as research institutions (RIs). In creating such a conducive environment for the development of the country's biotechnology sector, the Government launched the National Biotechnology Policy (NBP) in 2005.

The NBP provides for a more integrated framework of industry development, outlining a comprehensive set of goals, priorities and strategies. It is formulated so as to use biotechnology as a mechanism for spurring Malaysia's economic growth, enhancing the wealth as well as the prosperity of the country. The NBP is envisioned to further develop R&D and industrial biotechnology and strengthen the country's existing core competencies and infrastructure. As in the case of other Asian countries, government policy has provided the principal impetus for a biotechnology industry. Hence, at the initial stage, the Government will be the main driver for biotechnology development by providing strategic direction, infrastructure development and funding. This will provide an integrated platform for participation by scientific, business and funding groups to ensure an eco-system that is capable of sustaining Malaysia's growth and progress in biotechnology.

The NBP has nine strategic thrusts,[490] but for the purpose of this thesis, only four thrusts will be specifically discussed, being the most relevant to the area of research. Thrust number one is on agricultural biotechnology. For this thrust, the mission under the Policy is to transform and enhance the creation of value creation by the agricultural sector through biotechnology. The other important thrust is the fourth one, which is on R&D and technology acquisition. Under this thrust, the Malaysian Government is committed to establishing centres of biotechnology excellence through R&D, as well as technology acquisition. Thrust number seven, which is on the legal and regulatory framework, is equally significant and very much relevant to this thesis, as it aims to strengthen the legal and regulatory framework by reviewing ownership of IP and regulations relating to biotechnology processes and business. Finally, thrust number nine relates to the government's support and commitment in order to realize the execution of policy. This has been done through the establishment of a dedicated and professional government

[490] Refer <http://www.biotechcorp.com.my/biotechinmalaysia/nationalpolicy.htm> [Accessed 20 January 2009]

agency to spearhead the development of the biotechnology industry with the incorporation of the Malaysian Biotechnology Corporation (BiotechCorp). The targets that have been achieved by BiotechCorp to some extent serve as one of the vital yardsticks and measurement to the success of the biotechnology industry in Malaysia.[491]

As far as the NBP is concerned, the initiatives under the Policy are implemented within the timeframe of the Biotechnology Master Plan from 2005 to 2020, which embrace three phases: Phase 1 is on capacity building from the year 2005 until 2010, Phase 2 is on commercialization of biotechnology, which is to commence from the year 2011 until 2015, and finally Phase 3 which is targeted on the country emerging as a global biotechnology participant, which is planned to begin from the year 2016 to 2020 and beyond.[492]

At present, the focus is directed towards implementing the plans in Phase 1, which include the efforts to provide biotechnology development incentives, to improve human capital and skills development, to improve job creation, to intensify R&D, to accelerate development in agricultural biotechnology, to strengthen the legal and IP framework as well as to develop BioNexus companies.

In Phase 2, which is scheduled to commence in the year 2011 until 2015, the plans mainly include intensifying foreign direct investment participation and

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[491] The targets achieved by Biotech Corp in the development of biotechnology industry in Malaysia is published in its review – Refer The Biotech Review 2005-2007, Available at: <http://www.biotechcorp.com.my/pdf/270508c_final_report.pdf> [Accessed 02 February 2009]
[492] *Supra*, note 487, p.6.

technology acquisition, expanding the pool of knowledge workers, developing capability in technology licensing, improving new products development and to create global brands.

Phase 3 will continue with all the abovementioned plans but eventually the ultimate aim is to strengthen branding of Malaysia as a global biotechnology hub. A cursory look at all these plans would suggest that there is a lot of work to be done by the Government in particular, which in turn delegated to relevant ministries and agencies, most notably BiotechCorp from the very early stage of its establishment in the year 2005. The role of BiotechCorp will be discussed in greater detail in the latter part of this chapter.

By implementing its comprehensive Biotechnology Policy in a concerted and coherent manner, tapping into its rich natural resources and biodiversity, as well as building on its existing capabilities, Malaysia is hopeful of becoming a preferred destination for innovation and investment in biotechnology. In a published report by the BiotechCorp[493] measuring the progress of the Malaysian biotechnology sector, it is evident that many projects have been realized in accordance with the target. Since 2006, the outcome of successful partnerships and collaborations internationally and within Malaysia is reflected in the establishment and growth of biotechnology companies in Malaysia. Across sectors in agriculture, healthcare and industrial biotechnology, Malaysia continues to formulate and initiate collaborations and partnerships around the world – particularly in key learning and market centres in the U.S., South America, the UK, France, Germany, India, China, South Korea and Japan.[494]

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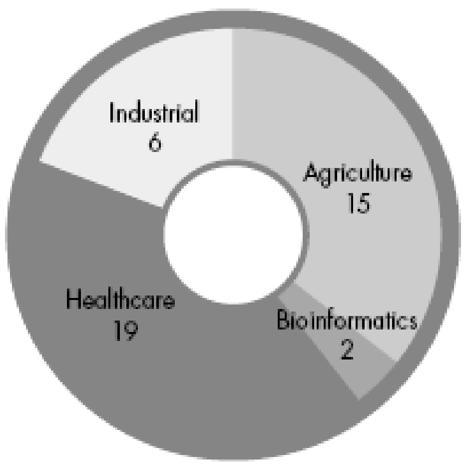
[493] *Supra*, note 489.
[494] *Ibid*., at p. 15.

4.2.1 BioNexus Status

Within the industry, BioNexus status was granted to 15 companies in agriculture biotechnology, 19 in healthcare biotechnology and 2 in bioinformatics from the year 2005 to 2007. Currently, a total of 137 companies[495] have been awarded with BioNexus status that span agriculture, healthcare and industrial biotechnology. BioNexus status is a recognition awarded by the Malaysian Government through BiotechCorp to qualified companies that participate in and undertake value-added biotechnology business. Such companies are generally entitled to certain tax incentives, as well as enjoying a set of incentives and privileges contained within the BioNexus Bill Of Guarantees.[496] The number of BioNexus companies and their total investment are shown in the charts below.

Chart 4.1

Number of BioNexus Companies according to specific sector (as at 31st December 2007).

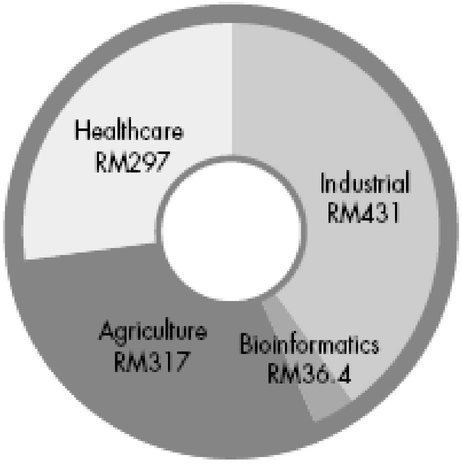


[495] As at December 2009. Source : Biotech Corp.
[496] *Op. cit.,* pp. 39-40.

Source: BiotechCorp

Chart 4.2

Total BioNexus Investment according to specific sector (RM mil).



Source: BiotechCorp

As far as project activities are concerned, in the field of agriculture, local biotechnology companies are involved in a range of activities, from plant genomics, animal health, diagnostics and biologics, fertilizer and soil enhancers, plant propagation via tissue culture, nutraceuticals, tissue culture to orchid tissue culturing. Broader efforts in building international alliances in agriculture biotechnology continue to be expanded through investment forums and stakeholder meetings with leading life sciences and biotechnology companies in the U.S., Germany and India. It is worth re-emphasizing that since Malaysia is essentially an agricultural country, agricultural biotechnology can be the right focus as biotechnological tools can be specifically applied to the different facets of agricultural activities already existing in the country.

All in all, based on the report and review published by BiotechCorp, it is observed that Malaysia is currently moving towards the right direction, albeit at a gradual and steady pace in developing its biotechnology industry. This is reinforced by the fact that the overall development of the biotechnology industry was encouraging and the company's ventures were bearing fruits in managing to generate revenue of almost half a billion ringgit by the end of year 2009.[497]

4.3 Legal and Regulatory Framework

4.3.1 The International Treaties

Malaysia is a member of the World Intellectual Property Organization (WIPO)[498] and a signatory to the Paris Convention[499] and Berne Convention[500] which govern IPRs. In 2006 Malaysia acceded to the Patent Cooperation Treaty[501]. In addition, Malaysia is also a signatory to the TRIPS Agreement[502] signed under the auspices of the World Trade Organization (WTO).

Therefore, Malaysia's intellectual property (IP) rights regime is in compliance with international best practice and provides for adequate protection to both local and foreign applicants. According to the Global Competitiveness Report 2009, Malaysia is ranked 37 out of 133 countries (refer Table 4.2 below) in terms of intellectual property protection and has one of the strongest IP regimes in Asia.

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[497] The Chief executive officer of Biotech Corp Datuk Iskandar Mizal Mahmood revealed the fact and figures during a media briefing on the BioMalaysia 2009 Conference and Exhibition in November 2009. Refer: http://melbio.com.my/index.php?option=com_content&view=article&id=50%3Abiotechcorp-on-track-to-help-21-new-bionexus-firms16102009&catid=29%3Afrom-bench-to-business&Itemid=18&lang=en> [Accessed 09 February 2010]

[498] Malaysia is a member of WIPO since January 1989.

[499] Malaysia is a signatory of Paris Convention since January 1989.

[500] Malaysia is a signatory of Berne Convention since October 1990.

[501] Malaysia is a signatory of PCT since August 2006.

[502] Malaysia is a signatory of TRIPS since January 1995.

Table 4.2

Global Competitiveness Report 2009 – Intellectual Property Protection

Rank	**Country**	**Score (1-7)**
1	Singapore	6.2
2	Sweden	6.1
3	Finland	6.1
4	Switzerland	6.1
5	Austria	6.1
6	Denmark	6.0
7	New Zealand	6.0
8	Luxembourg	5.9
9	Netherlands	5.8
10	France	5.8
20	Japan	5.4
23	Hong Kong SAR	5.3
27	Taiwan, China	5.0
37	Malaysia	4.5

Source: World Economic Forum, Executive Opinion Survey 2008, 2009

The TRIPS Agreement which is the main international instrument dealing with IPRs generally, prescribes minimum conditions that all member countries must incorporate into their laws for the protection of IPRs. As Malaysia is a member of the WTO, it must abide by the minimum standards of IP protection set in the TRIPS Agreement and is afforded flexibilities in its implementation. Therefore, in the year 2000, the Malaysian Parliament amended the Copyright Act 1987, the Patents Act 1983, the Trademark Act 1976, as well as legislation on layout designs of integrated circuits[503] and geographical indications[504] in order to bring Malaysia into compliance with its obligations under the WTO TRIPS Agreement. In 2004, Malaysia passed the 'Protection of New Plant Varieties Act 2004' (PNPVA) in line with the requirements of Article 27(3)(b)of the TRIPS Agreement. Malaysia's IP laws are in conformance with international standards and have been reviewed by the TRIPs Council periodically.[505]

Another important international instrument in relation to IP protection is the UPOV Convention, which was mainly created by breeders for the new crop varieties they developed and commercialized. The PVP laws of different countries were harmonized through UPOV 1978 and the latest version of 1991. The UPOV 1991 has considerably enhanced the protection afforded to breeders especially when compared to its 1978 version. As far as Malaysia is concerned, it is not yet a member of UPOV, though it has submitted its intention to join the treaty and has in fact initiated the procedure of accession to the UPOV Convention since the year 2004, after the passing of the PNPVA.

Other than the TRIPS Agreement, the PCT and the UPOV Convention, Malaysia also intends to be a party to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in the near future.

The enhancement of legal and regulatory expertise – with a focus on IP - is a key to the continued growth and progress of biotechnology. Hence, this

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[503] Layout Designs of Integrated Circuits Act of 2000.
[504] Geographical Indications Act 2000.
[505] Refer <http://www.mida.gov.my/en_v2/index.php?page=IP-protection> [Accessed 05 February 2009]

section will cover an examination of the current legislation affecting biotechnology with a specific focus on IP and related laws.

IP protection in Malaysia comprises of patents, trademarks, industrial designs, copyright, geographical indications and layout designs of integrated circuits, but for the purpose of this thesis, biotechnology law refers to the areas of law which span over a wide spectrum in the biotechnology industry including:
(i) IP protection, namely legally protected rights in the form of patents, as well as utility innovation for a lesser extent invention.
(ii) Protection by way of plant variety rights.

The primary function of biotechnology law as in other branches of law is to protect the interests of the parties involved, such as the protection of the invention by way of patent registration[506] and plant variety rights registration system. For example, the rationale behind granting a patent, other than to reward the inventor, is also to encourage public disclosure of an invention so that when the patent expires, the public can have free access to the invention. Thus, the ultimate goal of the patent process is to serve the public interest.

4.3.2 IP protection for agricultural biotechnological inventions in Malaysia: patent and PVP

As far as the Malaysian IP system is concerned, there are two main regimes which are currently in force; via patent law and plant variety protection law. Patent law in Malaysia refers to the Patents Act 1983, supplemented by the Patents Regulations 1986, while plant variety protection law in Malaysia is governed by the Protection of New Plant Varieties Act 2004 (PNPVA),

[506] HAMZAH, Zaid, 2005. *Biotechnology Law & Strategy.* Malaysia : Malayan Law Journal. p. 35.

supplemented by the Protection of New Plant Varieties Regulations 2008. These two methods of protection will be discussed in turn.

4.3.2.1 Patents Act 1983

The Patents Act 1983 and the Patents Regulations 1986 govern patent protection in Malaysia. A patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem. An applicant may file a patent application directly if he is domiciled or resident in Malaysia. A foreign application can only be filed through a registered patent agent in Malaysia acting on behalf of the applicant. Similar to legislation in other countries, an invention is patentable if it is new, involves an inventive step and is industrially applicable. In accordance with TRIPS, the Patents Act stipulates a protection period of 20 years from the date of filing of an application.

A similar right to patent is 'utility innovation', which denotes any innovation which creates a new product or process, or any new improvement of a known product of process, which can be made or used in any kind of industry, and includes an invention. For a certificate for utility innovation to be granted, absolute novelty is required as in an application for grant of patent. Thus, the novelty required is on a world-wide basis and is new if it has not been disclosed anywhere in the world. Nevertheless, by the definition in the 1983 Act of 'utility innovation', the requirement of inventive step is relatively low and more easily satisfied compared to that required for a grant of patent. In other words, it is an exclusive right granted for a 'minor' invention which does not require satisfying the test of inventiveness as required of a patent. Under the Act, the utility innovation certificate provides for an initial duration of ten years protection from the date of filing of the application and is renewable for further two consecutive terms of five years each subject to use. The owner of a patent has the right to exploit the patented invention, to assign or transmit the patent, and to conclude a licensed contract.

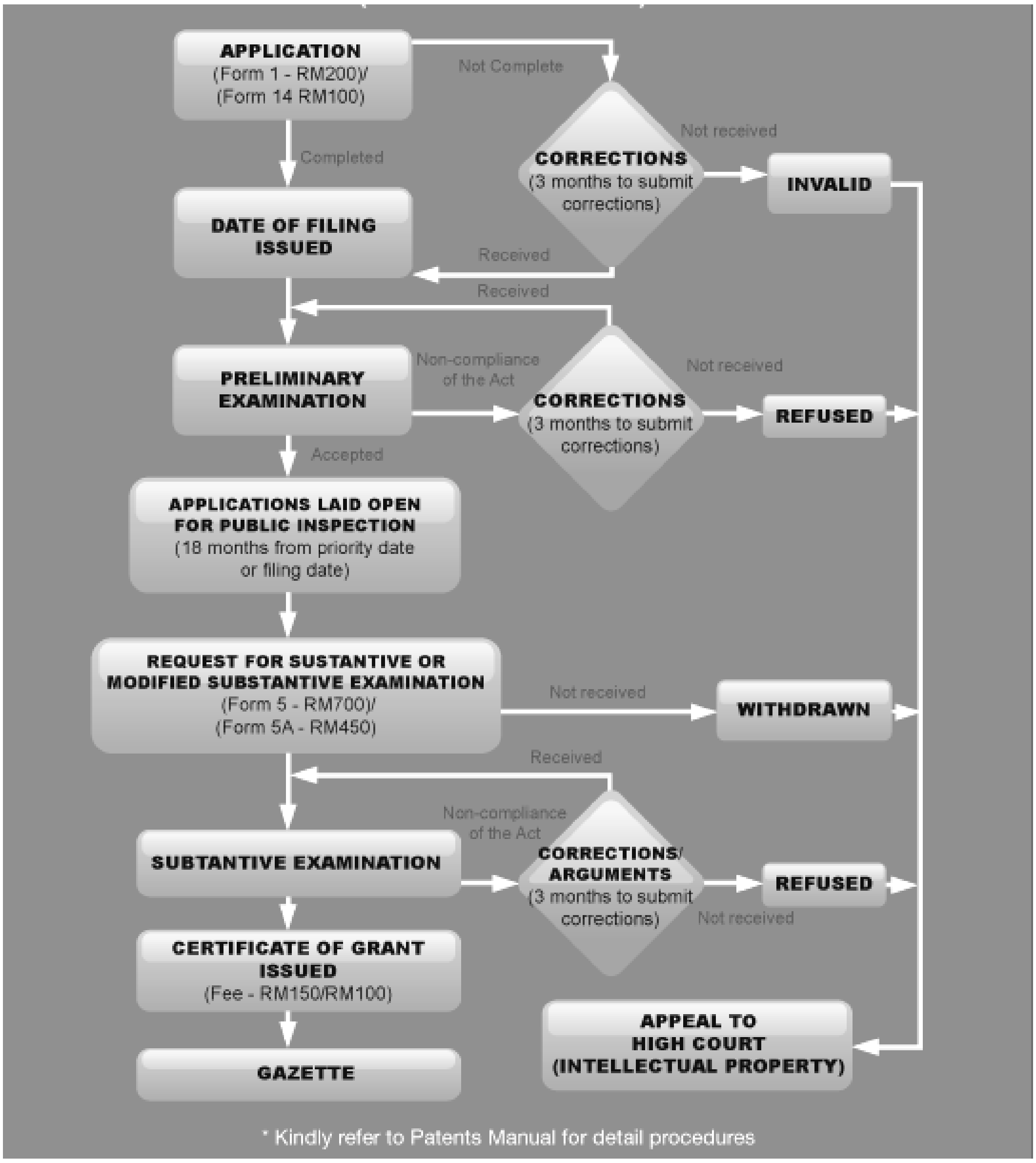
(i) Patent Registration Process

The flowchart[507] below shows the patent application procedure as administered under MyIPO, from the stage of submitting the patent application to the stage of preliminary and substantive examination before a certificate of grant is issued.

Chart 4.3

Flowchart Patent Application and Granting Procedure (Patents Act 1983)

[507] Refer : <http://www.myipo.gov.my/index.php?option=com_content&view=article&id=232&Itemid=265>



MyIPO has also confirmed that currently, the average of the whole process before a patent is granted ranges from four and half years to five years. It all depends on when the substantive examination is carried out, as the patent applicant may defer their request for substantive examination for up to 4 years.[508] As at July 2009, MyIPO Patent Division has 71 patent examiners, out

[508] Under Patent Regulations 1986, R27B(2) The prescribed period of maximum deferment is:
(i) 3 years from the filing date for requesting substantive examination;

of which 7 examiners specialize in engineering and biotechnology-related inventions.

Malaysia acceded to the Patent Cooperation Treaty (PCT) in the year 2006 and effective from 16 August 2006, the PCT International Application can be made at MyIPO. The PCT system enables the applicant to make a single application in Malaysia (the international application) and then 'designate' as many other countries that are involved in the PCT. It is to be noted that the PCT system is a patent 'filing' system, and not a patent 'granting' system, hence there is no PCT patent or international patent.

(ii) Scope of Patentability

In relation to the threshold of patentability under the Patents Act 1983, it generally follows the standard of other jurisdiction's patent regime, in particular the practice of the EPO. In other words, the threshold is at par with the international standard. Nevertheless, on the patent examination process, there is an emerging challenge encountered by patent examiners at MyIPO pertaining to the need for new knowledge, latest inventions and developments in biotechnology. One of the ways to enhance the knowledge, skills and expertise of the patent examiners is via intensive trainin for them in the field of biotechnology specifically.[509]

It is important to note that the Patents Act 1983 does not allow the patenting of animals or plant varieties or naturally-occurring microorganisms. The

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(ii) 4 years from the filing date for requesting modified substantive examination;
(iii) 3 years from the filing date for providing corresponding foreign search/examination results.
According to subsection 29A(7) Patents Act 1983, no deferment may be sought nor granted for a period greater than the 3 and 4 year periods referred to above.

[509] For example, the Establishment of Biotech Guidelines & Training of Examiners, 27 February – 10 March 2006, Kuala Lumpur.

express exclusion of patentability on plant varieties can be found in Section 13(2)(b) of the 1983 Act, which reads: '…the following shall not be patentable:

(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such microorganism processes.'

The Malaysian provision is consistent with the TRIPS Agreement as enshrined in Article 27.3(b). The above exclusion relates only to plant varieties, but inventions involving plants would generally be patentable. The position of a genetically modified variety is thus not patentable but a plant invention that consists of genetically modified cell-lines would be patentable. This means that a plant invention can only be registered under the breeder's system if it constitutes a variety.[510] At this juncture, it is to be noted that despite Malaysia's manifest intention to excel in the biotechnology industry, as far as its patent law is concerned, there has not been much effort in terms of amending Patents Act 1983 to reflect the envisaged goal. Nevertheless, MyIPO has recently started initiatives to review the IP related legislation to keep pace with the latest technological development, and the exercise will include the review of the Patents Act 1983.

As far as a patent application is concerned, MyIPO does not and has neither authority nor facility to accept any sample, specimen or prototype for any invention for all fields of technology. This is due to the fact that Malaysia is not yet a member of the Budapest Treaty on the International Recognition of the

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[510] AZMI, Ida Madieha Abdul Ghani, 2004. The Protection of Plant Varieties in Malaysia, *The Journal of World Intellectual Property.,* 7, pp. 877-890, at p. 882.

Deposit of Microorganisms for the Purposes of Patent Procedure. As of 31st January 2009, 72 countries are parties to the Treaty which allows a person who wishes to patent an invention internationally need only to deposit the microorganism at one recognized institution instead of in each country for recognition in all countries who are party to this treaty. This enhances efficiency in filing patents and is of significant benefit for the biotechnology sector in Malaysia. In relation to this, Malaysia is currently working towards the establishment of International Depository Authority (IDA). The IDA project is in fact a joint MyIPO-BiotechCorp project to establish and enhance patent procedure in Malaysia. The establishment of an IDA in Malaysia will ultimately complement the development of the biotechnology industry in Malaysia other than meeting Malaysia's future obligation under the Budapest Treaty.[511]

(iii) Patenting Activities in Malaysia

With regard to statistical data, the statistics of biotechnology in Malaysia are difficult to obtain as it is relatively a newly emerging industry, compared to other industries such as manufacturing. Hence, the properly documented current data on biotechnology patent is only available on general basis, for example, MyIPO confirmed that there was a total of 385 biotechnology patents application in the year 2008.[512]

The summary of patent biotechnology applications and granted applications from the year 1986 to 2008 as provided by MyIPO is incorporated in the table below:

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[511] *Supra*, Note 489, at p.30.
[512] Source : Patent Division, MyIPO.

Table 4.2

Statistics of biotechnology patent application and granted from 1986 - 2008

No	Application			Granted		
	Foreign	Malaysia	Total	Foreign	Malaysia	Total
Total	88,817	6,307	95,124	35,948	1,214	37,162
Biotech	-	-	2,387*	501	8	509

* Total applications Malaysia and foreign

Source: Patent Division, MyIPO.

Table 4.3

Statistics of biotechnology patent application 2008

Foreign (321)	Malaysia (64)				Total (385)
	Individuals	Universities	Research Institutes	Companies	
321	4	43	7	10	385

Source: Patent Division, MyIPO.

The above data and figures simply show that the country's rich natural resources and scientific expertise have not yet been commercialized to reap the optimum benefits. Local research and development has yet to lead to the application for new patents or launching of new biotechnology enterprises on a large scale. This is evidenced from the fact that by end of year 2008, only a total of 8 patents on biotechnology were granted to local applicants.[513] The table also shows that out of a total 385 biotechnology patent applications in 2008, only 64 came from Malaysia, and these local applicants range from individuals, universities, research institutes and companies. Local universities

[513] Source and data was provided by Patent Division MyIPO during the interview conducted at MyIPO office on 16th July 2009.

contribute to the highest number of applications; a total of 43 out of 64 biotechnology patent applications. This could be attributed to the fact that the Malaysian government in creating an enabling environment for biotechnology has been allocating substantial monetary funding for public universities, as well as research institutions, to be utilized in R&D, *inter alia* biotechnology research.[514] After all, R&D in biotechnology in Malaysia is dominated by the government funded RIs and universities, hence the statistics merely confirm and reflect the current scenario in the country.

Having said that, public sector institutions which have been undertaking the main responsibilities in biotechnology R&D are; Malaysian Agricultural Research and Development Institute (MARDI), Forest Research Institute of Malaysia (FRIM), Malaysian Rubber Board (MRB), Malaysian Cocoa Board (MCB), and Malaysian Palm Oil Board (MPOB). It is interesting to note that all these RIs are the patent owners of their research output on their respective fields, and this reflect their awareness on the importance of patent protection over their inventions.[515] For example, the first patent owned by MRB was granted as early as 1934 in relation to improvements relating to the treatment of rubber latex.[516] In additions, these RIs have a number of patents abroad in order to protect their inventions in other jurisdictions.

Coming back to the breeder's right and patent right, indeed, the boundary between breeder's right and patent right has been subject to various debates,

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[514] For example, under the Ninth Malaysia Plan (2006-2010), it is stated that the Biotechnology R&D Grant Scheme established in 2001 under the National Biotechnology Directorate approved a total of RM95.3 million for 47 biotechnology research projects, which includes public universities and research institutions.

[515] This observation is based on the semi-structured interviews which were carried out on these research institutions from April 2008 – October 2008. The detailed analysis of the interview is incorporated in Chapter 5.

[516] Refer <http://www.lgm.gov.my/general/patents.html>

as have been highlighted in the preceding discussion in Chapter Two of this thesis. There has yet to be any case in Malaysia that considers on the scope of the exclusion of patent rights on plant varieties. Cases from the UK and Europe as highlighted in Chapter Two thus, can lend significant assistance in understanding the issue.[517] As far as MyIPO's approach is concerned, the patent examiners at MyIPO are taking the stance that there is no overlapping and there should not be any overlap between patents and plant variety rights. This approach is based on the premise that criteria for patentable inventions are clearly spelt out in the 1983 Act, leaving little room for ambiguity. Practically, the patent examiner would screen all the patent applications submitted to the office from the very beginning, hence any applications that may amount to or may encroach the sphere of the plant variety right is rejected outright.[518] Nevertheless, the office has yet to encounter any such cases, as the patent agents are generally aware of the exclusion of plant variety from patentability as spelt out in the 1983 Act.

At this juncture, it is to be noted that MyIPO has produced the draft of its official guidelines for the examination of biotechnological patent applications. MyIPO is currently in the course of finalizing the draft, subject to the response of stakeholders via various meetings and discussions.[519]

(iv) Patent registration procedure

An application for a patent in Malaysia must be filed with the Patent Registration Office of MyIPO. The Patent Registration Office is responsible for

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[517] AZMI, Ida Madieha Abdul Ghani, 2003. *Patent Law In Malaysia: Cases and Commentary,* Malaysia: Sweet & Maxwell Asia. p. 313.
[518] This approach is confirmed by Patent Division MyIPO during the interview conducted at MyIPO office on 16th July 2009. The latest update from MyIPO received via email in September 2010 confirmed that the draft was yet to be finalized.
[519] *Ibid.*

the administration, processing and registration of patents and certificate for utility innovations. The application may be submitted to the Patent Registration Office by hand or mail.

Alternatively, the application may be submitted through an online filing system under PANTAS[520]. The online filing system was introduced for the purpose of providing a more systematic system and database, as well as to speed up the patent filing process. MyIPO has been able to grant patent in the fourth year from the date of filing provided all requirements are fulfilled. For the purpose of this thesis, a quick and random search via PANTAS had been carried out with the aim of collecting some useful and relevant data with regard to agricultural biotechnology patents filed with MyIPO. The search under 'plant' patent category revealed that there are approximately 1865 patents which are related to the broad category of plants.[521] Nevertheless, one of the limitations of PANTAS is that the current database does not include the applications below 18 months from the date of application.

A further search of the patents which are related to plants shows that a substantial number of patents are filed and granted under the wide heading of process or method, for example, 'a method and composition for the production of transgenic plants'.[522] A detailed search[523] on some these type of patents evidenced that MyIPO has no problem in granting patents on methods of producing a transgenic plant. For example, Malaysian Patent Number (PN) MY-135879-A is a patent granted on 'methods for producing genetically modified

[520] Refer : <https://pantas.myipo.gov.my> [Accessed 13 September 2010]
[521] *Ibid.,* The figure is correct as at September 2010.
[522] *Ibid.,* Application Number : 20013705, status : adverse full substantial examination, filed on 13/08/2001.
[523] This kind of detailed search attracts some fees, payable to MyIPO, at the rate of MYR 30.00 per patent details download.

plants, particularly woody plants, and most particularly plants of the eucalyptus and pinus species, involving transformation of target plant material with a desired genetic construct..'[524]

An interesting discovery was also made during the random search via PANTAS. For example, a patent filed on 5th June 2000 under the title 'seedless tomato'[525] was deemed refused, whereas a patent on herbicide resistant rice[526] was granted on 31st January 2008. These data reflect the approach taken by MyIPO in dealing with the issue of patenting transgenic plants, as there is no express provision in the Patents Act 1983 on patentability of transgenic plants. Hence, it is submitted that those transgenic plants are patentable under patent laws in Malaysia, as the only exclusion is meant for plant varieties.[527] Back to the above examples of refusal of patent on seedless tomato, one of the refusal grounds[528] is probably on, *inter alia* the very broad extensive patent claim, as the patent title itself reads 'seedless tomato and method for producing a seedless tomato, hybrid tomato plants capable of producing said seedless tomatoes and cultivation material therefore, and food products obtained from said seedless tomatoes.' It is doubtful whether the patent, say if granted, would cover the broad 'food products obtained from seedless tomatoes.' Nevertheless, it is to be noted that the actual reasons behind the rejection of the seedless patent tomato were unascertainable during the online random search, as there was a certain amount of fees imposed to extract the details of the patent application in the PANTAS database.

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[524] PANTAS, *op. cit.*, Patent Application Number : 20001005, granted on 31st July 2008.
[525] *Ibid.,* Patent Application Number : 20002511.
[526] *Ibid.,* Malaysian Patent (PN) MY-134925-A.
[527] Section 13 (1)(b) Malaysian Patents Act 1983.
[528] PANTAS does not provide details of refusal of a patent claim.

(v) Patent Classification

In terms of classifying a patent application, to ascertain whether an invention falls under the biotechnology class, patent examiners are currently using the International Patent Classification (IPC) as their reference. In other words, all patent applications submitted to MyIPO will go through the 'screening process' under the preliminary examination[529] in order to determine whether a patent application falls under biotechnological classification.

At this stage, the title of the application and its abstract as submitted to MyIPO plays a vital role in establishing the class of the invention. The IPC which was established by the Strasbourg Agreement 1971, and provides for a hierarchical system of language independent symbols for the classification of patents and utility models according to the different areas of technology to which they pertain.[530] The IPC which is utilized by Patent Division of MyIPO is produced below:

Table 4.4

International Patent Classification (IPC) – Biotechnological Invention

No	IPC	Type Of Class
1	A01H	Transgenic Plants
2	A01N 39/00- 39/65	Moas Pesticides
3	A01K 67/027	Transgenic Animal
4	A61K 48/00	Gene Therapy
5	A61K 38/00	Medicinal Preparation
		(Pharmaceutical)
6	A61K 39/12	Viral Antigen
7	A23J,C,L	Food Fodder
8	C12N9	Enzymes

[529] R26 of the Patent Regulations 1986.
[530] A guide to the IPC 2009 version is available at WIPO's website. Refer < http://www.wipo.int/export/sites/www/classifications/ipc/en/guide/guide_ipc_2009.pdf>

9	C12N11	Enzymes
10	C12N15	Genetic Engineering
11	C12N1	Bacteria
12	C12N5	Cell Culture
13	C12N7	Virus
14	C07K 14	Pepticides
15	C07K 17/705	Receptors
16	C07K 16	Antibodies
17	C07K 14	Peptides
18	C12N 9	Peptides
19	C07K 16	Peptides
20	C07K 16	Antibodies
21	C12P 21/06	Antibodies
22	C12Q 1/68	Gene Diagnostic, Amplifications,
		Diagnostic Antibodies
23	C12R 1/00	Microorganism
24	C12P	Fermentation Chemicals
25	C12G	Alcoholic Beverage
26	G01N 33/53	Diagnostic Immunassy
27	C11D 3/386	Detergent Preparation
28	C21H 21/00	Paper Industries
		Enzyme To Make Paper
29	D06M 16/00	Enzymes Use In Textile

Source: Patent Division, MyIPO.

The examination process of every patent application which is submitted to MyIPO is conducted by three different sections of Patent Division namely the Formality Section, the Engineering Section and the Applied Science Section. The biotechnological patent examination is under the responsibility of the Applied Science Section.

It is observed that the dedicated, skilled team of patent examiners under MyIPO has been one of the significant driving forces towards a strong legal infrastructure and effective administration. Such dedication and skills are important to enhance greater creativity and exploitation of intellectual property in general, and a more efficient patent system in Malaysia in particular.

4.3.2.2 Protection of New Plant Varieties Act 2004

Since the early nineteenth century, in agriculture and forestry, the introduction of new varieties was an essential component to maintain and sustain good and high crop productivity and quality. New varieties are constantly being bred for higher yields, for better agronomic traits like taste, for resistance against pest or diseases, for tolerance to saline or drought conditions. Malaysia sees the introduction of new varieties of plants as an important component in commercial agriculture in terms of maintaining productivity and competitiveness. Breeding of new varieties of plants essentially requires substantial investment in terms of time, skills, labour, material resources and capital. In order to encourage such investment, the Malaysian Government has taken the necessary step with the main aim to provide exclusive rights to plant breeders to enable them to recover their investment and also to reap benefits of their innovative skill and creativity.[531] The approach is in fact in consonance with the Third National Agriculture Policy (1998-2010).[532]

[531] Agriculture minister wants introduction of new varieties of plants, Available at: < http://biz.thestar.com.my/news/story.asp?file=/2006/11/6/business/20061106175335&sec=business> [Accessed 05 February 2009]

[532] The policy paper outlines the government's policy on the development of the Malaysian agriculture sector. Refer <http://www.moa.gov.my/moa/index.php?option=com_content&task=blogcategory&id=212&Itemid=152> [Accessed 05 February 2009]

Being a member of the WTO and a signatory to the TRIPS Agreement, which under Article 27(3)(b), stipulates that member countries shall provide for the protection of plant varieties by a patent or by an effective *sui generis* system or by any combination thereof, Malaysia has been under pressure to put into place a protection regime for plant varieties. In this sense, the promulgation of the Protection of New Plant Varieties Act 2004 constitutes a step in the right direction.[533] Other than fulfilling its obligation under the TRIPS Agreement, the Act was introduced with a number of significant aims, *inter alia*, to encourage local plant breeders to produce more superior varieties, while local farming communities can also have greater access to more superior varieties from abroad. The Act also provides recognition and protection of contribution made by farmers, local communities and indigenous people towards the creation of new plant varieties,[534] as well as encouraging investment and development of the breeding of new plant varieties in both public and private sectors.

With regard to the creation of new plant varieties, an informal breeding system has already been in place since the 1930s, from which time the Malaysian Department of Agriculture (DOA) registered fruit clones for certification purposes. However, this informal system does not bring about a formal protection for the creators of varieties. Since then, more than 100 varieties of *durian* (an edible fruit) have been registered, 200 varieties of *mangoes*, 35 of jackfruits, and 40 of *cempedak* and other varieties of fruit plants. This informal registration of the breeding system is part and parcel of the larger current interest in recording the biological resources in the country

[533] AZMI, *supra* Note 515.
[534] Section 13(1) Protection of New Plant Varieties Act 2004.

as well as documenting traditional varieties.[535] The DOA was officially acknowledged as the National Registrar of Varieties in 1994 by the Ministry of Agriculture. Therefore, the responsibility in implementing the 2004 Act has been entrusted to the DOA.[536]

It is equally interesting to note that the 2004 Act is essentially a pan-Malaysian by nature, which is applicable to all plants but excludes microorganisms.[537] The drafting of the Act was done through consultation process with various relevant ministries and other government agencies, research institutions and non-governmental organizations including the Third World Network.[538] The main provisions of the Act were substantially based on the UPOV model 1978 version, due to the fact that at the time when the work on drafting of the Act commenced, the UPOV 1978 version was the only model available at that time.[539] Hence the Act bears significant resemblance with the UPOV 1978, besides the reference to the Convention of Biological Diversity (CBD) and existing IPR systems in Japan, Australia, India and Thailand.

The 2004 Act is 'unique' to meet the needs of the country and protects small farmers and local researchers. Notably, the Act contains unique stands on various issues such as traditional varieties, farmers' rights, indigenous peoples and local communities' rights. This is reflected in the Preamble of the Act which states the objectives of the Act as 'to provide for the protection of the rights of breeders of new plant varieties, and the recognition and protection of

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535 AZMI, *op.cit.,* pp. 877-878.
536 Refer http://pvpbkkt.doa.gov.my/> [Accessed 10 February 2009]
537 Section 2 (Interpretation of 'plant') of the Protection of New Plant Varieties Act 2004.
538 AZMI, *supra* Note 430, p. 878.
539 This is confirmed by the Malaysian Plant Variety Office during the (semi-structured) interview session on 24th July 2009, held at the Plant Variety Office, Department of Agriculture at Putrajaya, Malaysia.

contribution made by farmers, local communities and indigenous people towards the creation of new plant varieties; to encourage investment in and development of the breeding of new plant varieties in both public and private sectors; and to provide for related matters.'

(i) Salient features of the Protection of New Plant Varieties Act 2004

(a) Threshold of registrability

The 2004 Act adopted the UPOV system and mandates the threshold of registrability to be new, distinct, uniform and stable,[540] hence the practice of examination of plant varieties in Malaysia is to be on a par with international practice. The kind of exclusive rights granted to the breeder are also consistent with that of the UPOV Convention. Section 30(1) of the Act expressly provides that: '…a holder of a breeder's right shall, in respect of the registered plant variety for which the right is granted, have the right to carry out all or any of the following acts on a commercial basis:

(a) producing or reproducing;

(b) conditioning for the purpose of propagation;

(c) offering for sale;

(d) marketing, inclusive of selling;

(e) exporting;

(f) importing;

(g) stocking the material for the purposes mentioned in

paragraphs (a) to (f).'

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[540] Section 14(1) of the Act.

Subsection(2) of the section further clarifies the scope of the breeder's right: 'The breeder's right shall also extend to —

(a) any propagating material of the registered plant variety, harvested material of the registered plant variety and the entire or any part of a plant variety where the propagating material of that plant variety is obtained through unauthorized means from the registered plant variety;

(b) plant varieties which are essentially derived from the registered plant variety, if the registered plant variety is not essentially derived from another plant variety;

(c) plant varieties which are not clearly distinguishable from the registered plant variety; or

(d) the production of other plant varieties which require the repeated use of the registered plant variety.

(b) Essentially derived varieties

It is clear from paragraph (c) of subsection (2) that the scope of breeders' rights in Malaysia encompasses the 'essentially derived varieties'. The definition of this term has been discussed in Chapter 2 of this thesis, being one of the important enhancements in the UPOV 1991 version. In this regard, the 2004 Act apparently incorporates the provision of the latter version of UPOV, notwithstanding the fact that most of the provisions are based on the earlier version, namely the UPOV 1978. The incorporation of the term 'essentially derived varieties' in the 2004 Act could be attributed to the intended aim of the Act in order to provide strong protection to the breeders. This could be done by preventing the exploitation of mutations of protected varieties, as well as varieties that had undergone a minor change in relation to the initial variety without the holder or the owner of the initial variety right being able to share in the revenues.

(c) Limitation of breeder's rights

Another important provision is with regard to the research exceptions, as breeders are always concerned whether they will be restrained from researching on the registered varieties with the intention of developing new ones. Section 31(1) of the Act caters for such a concern: 'The breeder's right shall not extend to —

(a) any act done privately on a non-commercial basis;

(b) any act done for an experimental purpose;

(c) any act done for the purpose of breeding other plant varieties and any act referred to in paragraphs 30(1)(a) to (g) in respect of such other plant varieties, except where such other plant varieties have been essentially derived from the registered plant variety;

(d) any act of propagation by small farmers using the harvested material of the registered plant variety planted on their own holdings;

(e) any exchange of reasonable amounts of propagating materials among small farmers; and

(f) the sale of farm-saved seeds in situations where a small farmer cannot make use of the farm-saved seeds on his own holding due to natural disaster or emergency or any other factor beyond the control of the small farmer, if the amount sold is not more than what is required in his own holding.'

The above provisions on the research exceptions generally accord with the UPOV 1991.[541] This so-called 'research exemption' is particularly important for breeders, who traditionally work by incremental improvement of existing materials. If they do not have access to new materials, to make further improvements, their work is severely hindered. It follows from this, that it is never an infringement of a plant variety right if a breeder were to use the variety for further breeding. This does not include, of course, the use in commercial production. Equally, in general, it is not an infringement of a PVP to exploit or sell the new variety bred.

(d) Farmers' Privilege

Subsections (d) to (f) of Section 31(1) are the three special exceptions to cater for the small farmers. This is to ensure that farmers are not economically penalized by the conferral of exclusive rights over plants and propagating materials.[542] It is to be noted that such privileges can only be claimed by 'small farmers', which denote farmers whose farming operation do not exceed the size of holding as prescribed by the Minister. The Protection of New Plant Varieties Regulations 2008 in Section 2 defines the term 'small farmer' as that the size of his or its holding for farming operations shall not exceed 0.2 hectare. The determination of the size of the land namely 0.2 hectare was done by reference to the average size of the farm owned by ornamental flower producers and growers. This is parallel to the objectives of the 2004 Act namely to protect the interests of the local farmers and breeders, and this

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[541] Refer Article 15(1) UPOV 1991: [Compulsory exceptions] The breeder's right shall not extend to
(i) acts done privately and for non-commercial purposes,
(ii) acts done for experimental purposes and
(iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.
[542] AZMI, *supra* Note 515, p. 890.

includes ornamental flowers' producers and growers, whom largely fall under the category of 'small farmers' under the Act.

Initially, during the drafting stage of the Regulation, the size of the land in relation to small farmers was proposed as 1.2 hectare with reference to a paddy farm, but ultimately after the process of negotiation with the relevant agencies and authorities, the figure of 0.2 hectare was finalized to be incorporated into the Regulation to denote small farmer. This size of farm is essentially meant for all types of farmers inclusive of paddy, ornamental flowers, fruits, as well as other types of plants. At this juncture, the protection under the Act which is available to small farmers is also automatically available for those farm owners for hobbies purpose, for example to grow and cultivate ornamental flowers on house compound, as long as the farm does not exceed 0.2 hectare.[543]

With these exceptions, the long held reservations against the perceived inequities that farmers may suffer as a result of exclusive rights over plants and propagating materials would diminish considerably. In fact, the special privileges granted to farmers accords with the optional exception in Article 15(2) of the UPOV Convention in allowing contracting parties to: '…restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety…'. The Malaysian provision, however, goes beyond the context of

[543] The source is based on the interview; *supra*, Note 536. The statistics of the current percentage of small farmers in Malaysia is not available, due to the fact the term 'small farmers' also encompasses individual owners, whose farming is based on hobbies and personal interests, and the land is part of their house compound/residence.

Article 15(2), as it also legitimizes the exchange of harvested materials among small farmers, in addition to the propagation of such materials. In cases of emergency, the farmers are even allowed to sell the farm-saved seeds to others.[544]

(e) Traditional Variety

One of the unique parts of the 2004 Act pertains to the traditional variety or a variety developed by the local community. The threshold of registration for traditional varieties is somewhat lower than the usual UPOV-type system, namely new, distinct, uniform and stable as the criteria. With traditional varieties, the plant variety may be registered if it is new, distinct and identifiable.[545] The requirements of uniformity and stability are waived in relation to traditional varieties, and they enjoy a much shorter period of protection, that is fifteen years.[546]

The lower threshold for traditional varieties is parallel to the objective of the Act in order to give protection and recognition of contribution made by farmers, local communities and indigenous people towards the creation of new plant varieties, specifically the traditional varieties. Most significantly, the provision reflects the express recognition to the contribution made by farmers to the national agricultural industry.[547]

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[544] *Ibid.*
[545] Section 14(e) of the 2004 Act: a plant variety is identifiable if— (i) it can be distinguished from any other plant grouping by the expression of one characteristic and that characteristic is identifiable within individual plants or within and across a group of plants; and (ii) such characteristics can be identified by any person skilled in the relevant art.
[546] Section 32(1)(b) of the Protection of New Plant Varieties Act 2004.
[547] AZMI, *supra* Note 515, pp. 888-889.

Obviously, Malaysia is adopting a *sui generis* approach in designing and incorporating a unique system for protection of traditional varieties in the 2004 Act. The protection is of paramount importance for local farmers' interests in Malaysia. It is to be noted that under normal circumstances of the UPOV criteria, farmers' varieties are unlikely to gain protection as new plant varieties since it would be difficult for farmers to show that their varieties meet these conditions. As a matter of fact, farmers' varieties in Malaysia, for example rice varieties planted by traditional rice farmers are highly diverse and, by virtue of their *in situ* cultivation, keep evolving in the field and exhibit new characteristics as a result of adaptation to changes in the ecology. While they are distinct and identifiable, they may not be uniform or stable. In this regard, the 2004 Act is an important avenue for traditional farmers, local communities and indigenous people to obtain legal protection and due recognition for their contribution in the country's plant breeding sector as a whole.[548]

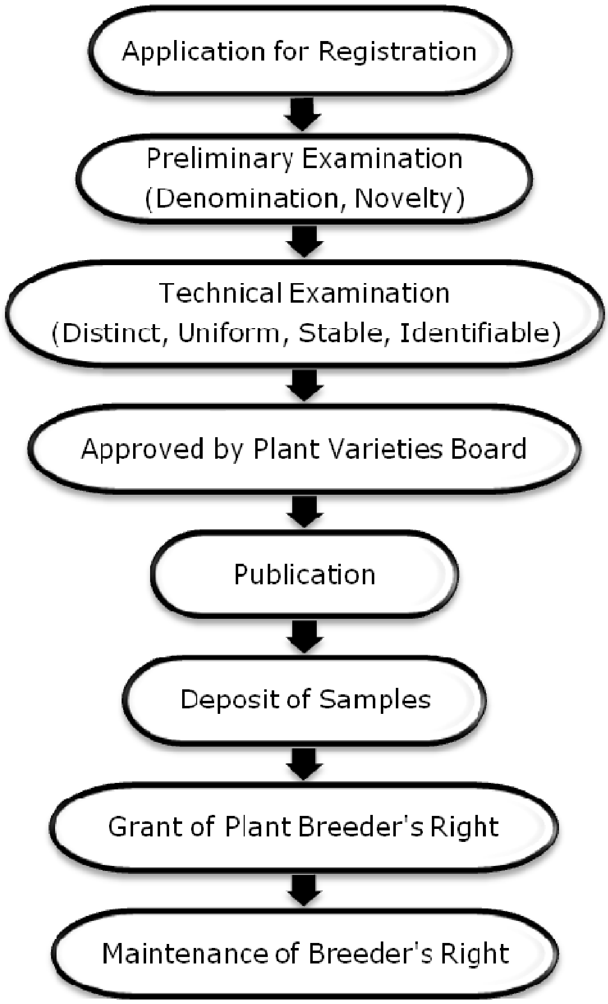
(f) Process of Application

The processes and stages of obtaining a protection for new plant varieties are summarized in the following flow chart:

[548] Some example of traditional varieties of rice are 'Beras Bajong' and 'Beras Biris' which are developed and planted by traditional local farmers of Sarawak. These two promising varieties have recently been given certification by Department of Agriculture. Refer newspaper report at : < http://www.theborneopost.com/?p=598> [Accessed 11 February 2010]

Chart 4.4

Flow chart for registration and grant of breeder’s right



Source: Malaysian Department of Agriculture (DOA)

The estimated duration from the stage of filing an application for registration until the grant of breeder’s right varies depending on the type of plant variety. The technical examination would consume the longest duration to ascertain the requirement of ‘distinct, uniform, stable and identifiable’ of the variety. The substantive examination via on-site inspection and a growing test is very much dependant on the type of plant. For example, for short term crops or plants, the examination process range from twelve to twenty-four months; for an intermediate term plant such as rubber tree, it ranges from twenty-four to sixty months; whereas for a long-term crop like oil palm, it ranges up to hundred and twenty months (approximately 10 years).

At this juncture, it is relevant to note that it is the normal practice of an applicant who wants to file an application in order to obtain the certificate of plant breeders' right to plant the crop like oil palm at their own plantation for them to do their own monitoring and assessment. Hence, in most instances, the plant or crop namely the oil palm has already reached its eighth year when the application is submitted to the plant variety office. The examination by examiners from DOA would then be carried out for the remaining two years duration. Therefore, the whole examination process takes up to ten years wholly. The reason of DOA to start the examination at the eighth year after the oil palm is planted is due to the unique traits of oil palm which is found to be stable after the eighth year of its planting. Nevertheless, it is admitted by the DOA that there may arise some difficulties for foreign application or application from abroad seeking for protection under the 2004 Act, as their crop is required to be replanted in Malaysia for the examination purposes before a certificate of breeder's right can be granted.

The particular specific duration which is required for examination is essential to assess and ascertain the stability of a plant variety before the grant of the breeder's right. The examination is exercised based on the Administrative Guidelines On Application And Registration Of New Varieties Of Plants 2008.[549]

[549] Available at: <http://pvpbkkt.doa.gov.my/>

As far as the presently introduced system is concerned, it differs from the informal registration system in a few aspects. One of the differences is, the informal registration system which has been in place since 1930's was merely a register and listing, and was not based on the international standard. Hence, there is no protection afforded to the plant breeders even though they opted to register their varieties in the register. The listings or register which was done on voluntary basis and administered under the DOA, was mainly for the purpose of updating the information, as well as to facilitate the commercialization in the event that the breeder decided to grow the variety on a large scale. This is because, as part of the process and procedure, there was a need for a proper committee to be set up, as well certain presentation of the proposed project to be done for the approval by the horticulture unit under the DOA.[550]

(ii) The implementation of the Protection of New Plant Varieties Act 2004

With regard to the implementation of the 2004 Act, the Protection of New Plant Varieties Regulations 2008 has been gazetted and came into operation on 20th October 2008. Following this, the Malaysian PVP office started to accept applications for registration from 1st November 2008. Applications are made using form PVBT 1 together with the guidelines and appropriate technical questionnaire.[551] Foreign applications can be made through an agent who is a resident or who has a registered office in Malaysia. The Regulations substantially cover the important aspect of the breeder's right system such as the filing of application, preliminary and substantive examination, deposit of

[550] The source of information is based on the interview; *supra*, Note 536.
[551] *Op.cit.,* refer the guidelines.

samples, registration of new plant variety and grant of breeder's right as well as compulsory licence.

At present, there are 45 examiners nationwide who work for research institutes, government agencies, and the like. This includes 16 examiners who work exclusively for the DOA. The New Plant Varieties Test Center in Serdang Selangor which was established in the year 2008, is equipped with facilities such as fields and greenhouses for conducting growing tests.[552] In order to enhance the examination skills and expertise of the examiners, training has been conducted in Malaysia. For example, in March 2009, the "Domestic Training Program on the Plant Variety Protection System" was held as a part of the specialist dispatching project of the East Asia Plant Variety Protection Forum, focusing on ways of conducting growing tests and on-site inspection.[553]

The summary of the plant varieties application is published on the Malaysian Department of Agriculture's (DOA) website[554] and the list is updated regularly. As at September 2010, the total number and status of application are as follows:

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552 Refer <http://www.eapvp-forum.org/topics/2009/20090320_04.html> [Accessed 14 September 2010]
553 *Ibid.*
554 Refer <http://pvpbkkt.doa.gov.my/>

Table 4.6

Number of application for plant varieties application submitted to the DOA

Plant Varieties	Cumulative Number Of Applications December 2008 – September 2010
Fruits	6
Ornamentals	7
Industrial Crops	9
Forest Pants	19
Cereals	11
Vegetables	1
Mushroom	1
TOTAL APPLICATIONS	54

Source: DOA

Table 4.7

Status of the plant varieties application

Status Of Application	Cumulative: December 2008-September 2010
Application Accepted	54
Application Granted PVR	0
Application Withdrawn	0
Application Refused	0
Application Revoked	0
Application Cancelled	0

Source: DOA

The total number of the application which has been received by the PVP Office for a period of 22 months (December 2008 – September 2010) is relatively small and this could be attributed to the fact that the PVP Regulation is still new and has been in force since October 2009. It is expected that more applications will be received by the PVP Office in the year 2011 from various government agencies such as MARDI which is actively carrying out the on-going agricultural-based researches. The PVP Office's target was to receive a total of 50 applications by end of 2010 and apparently the target was achieved.[555] The Office also confirmed that they have received numerous inquiries on the matters related to the registration procedures of the new system, which shows to some extent escalating interest in the protection of plant varieties among Malaysian plant breeders. As far as the applications are concerned, a high percentage comes from the research institutions like MARDI which filed applications to protect its R&D findings and invention, whereas the remainder comes from private companies, which include, *inter alia,* the application to protect new varieties of mushroom and pineapple.

In is interesting to note that the PVP Office has pro-actively promoted the newly introduced system of protection for plant variety via various awareness programs such as seminars for public and plant breeders. The effort is significant towards achieving the objectives of the 2004 Act in particular, even though there has yet to be any application from indigenous people to protect their plant variety. As has been mentioned in the preceding discussion, one of the important objectives of the 2004 Act is to provide recognition and protection of contribution made by farmers, local communities and indigenous people towards the creation of new plant varieties. In fact, one of the teething challenges encountered by the Office is to identify and encourage breeders from small industry to submit applications for protection under the new system. For example, ornamental flower growers and producers in Cameron

[555] *Supra*, note 536.

Highlands Pahang are not really interested in application due to lack of awareness of the benefits from the protection of their variety. In addition, they have been relying on foreign seed producers for their ornamentals, hence there is a lack of initiatives and interest in producing their own new variety.

In short, the newly introduced *'sui generis'* system of protection plays an important part towards providing the protection of the rights of breeders of new plant varieties as well as in development of legal protection for agricultural biotechnology in Malaysia.

(iii) Towards UPOV accession

It should be noted that as at to-date, Malaysia has yet to become a Member of UPOV. Although the current Malaysian Act can be said to be 90 percent UPOV-compliant, some provisions would have to be amended if Malaysia were to ratify UPOV 1991. By virtue of Article 34(2) of the 1991 Act, it therefore has to deposit an instrument of accession in order to become a Contracting Party on the basis of the 1991 Act. Under article 34(3) of the 1991 Act, an instrument of accession can only be deposited if the State in question has requested the advice of the UPOV Council on the conformity of its laws with the provisions of the 1991 Act and if the decision of the Council embodying the advice is positive.[556]

Malaysia has the intention of joining the UPOV fraternity with the aims *inter alia,* to enable access to improved foreign varieties such as ornamental

[556] UPOV Document – Twenty Second Extraordinary Session: Examination Of The Conformity Of The Protection Of New Plant Varieties Act 2004 Of Malaysia With The 1991 Act Of The UPOV Convention, 2005. Available at: <http://www.upov.int/en/documents/c_extr/22/c_extr_22_2.pdf> [Accessed 12 February 2009]

flowering plants from UPOV member countries, as well as to profit from the rich experience developed under the UPOV Convention, in particular regarding the technical guidelines adopted, and from the technical assistance that the UPOV could provide. In order the realize this intention, it has submitted its application in November 2004[557] requesting the UPOV Council to conduct a preliminary examination on the conformity of the Malaysian 2004 Act in relation to the provisions of the 1991 Act of the UPOV Convention.

After the preliminary examination of the UPOV Consultative Committee, the Council reported[558] that although its main provisions incorporates most of the substance of the 1991 Act, the 2004 Act still required some additional provisions and amendments, (as provided in document C(Extr.)/22/2),[559] in order to remedy the deviations from strict conformity, hence to fully conform with the 1991 Act. The Council accordingly advised that the Act would need to be resubmitted to the Consultative Committee once the additional provisions and amendments had been incorporated.

As far as the examination is concerned, the UPOV Council has highlighted a number of provisions in the 2004 Act which is not in conformity with the 1991 Act (and hence need to be amended). For example, it pointed out that the rights granted under Section 14(2) of the 2004 Act fall outside the scope of the 1991 Act, since they refer to a specific group of applicants, a different subject matter, different conditions of protection and a different duration of

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[557] This is based on the official letter submitted by Malaysian Department of Agriculture to the UPOV Vice Secretary-General dated 10th November 2004.
[558] Refer <http://www.upov.int/export/sites/upov/en/documents/c_extr/22/c_extr_22_3.pdf> [Accessed 12 February 2009]
[559] AZMI, *supra,* Note 508.

the right. Section 14(2) of the Act reads: 'Notwithstanding subsection (1)[560], where a plant variety is bred, or discovered and developed by a farmer, local community or indigenous people, the plant variety may be registered as a new plant variety and granted a breeder's right if the plant variety is new, distinct and identifiable.' The UPOV Council was of the view that the rights granted under subsection (2) that requires a variety to be new, distinct and identifiable, would have the possible impact of hindering the protection under subsection (1), that is the application of the provisions of the 1991 Act, which requires the plant variety to be new, distinct, uniform and stable in order to qualify for the protection. In this regard, it was the Council's recommendation to clearly separate the provisions dealing with that particular right from the provisions modeled after the 1991 Act.

With regard to the Council's recommendation, it is apparent that the provision on the lower threshold of registrability for traditional varieties is of paramount importance which is purposely incorporated for the protection of the rights of informal breeders which include farmers, local communities and indigenous people, hence to separate the provision from the current 2004 Act is neither viable nor justifiable. After all, the provision is parallel and in fact the reflection of the Preamble to the Malaysian PVP Act which provides for three objectives of the Act, one of which is for the recognition and protection of contributions made by farmers, local communities and indigenous people towards the creation of new plant varieties. Perhaps one possible way to comply with the UPOV's Council recommendation but at the same time to uphold and maintain these rights is by having a totally separate Act for the

[560] Subsection (1) reads: 'Subject to sections 15 and 16, a plant variety shall be registered as a new plant variety and granted a breeder's right if the plant variety is new, distinct, uniform and stable.'

exclusive protection of farmers, local communities and indigenous people in Malaysia. Having said that, it is worth noting the process of drafting until the final process of passing an Act by Malaysian legislature is a very long, painstaking process, before a new Act could be passed and implemented, hence to produce a separate Act for the protection of farmers is possible yet time-consuming. It took Malaysia ten years from the time it first embarked on the process to finally pass the Malaysian PVP Act (PNPVA).

Another example from the analysis of the UPOV Council is concerning the genera and species to be protected. The 2004 Act does not provide for the genera and species to be protected. The Council pointed out that, in accordance with Article 3(2)(i) of the 1991 Act, when depositing its instrument of accession, Malaysia must notify a list of at least 15 genera and species to which it has to apply the 1991 Act. Hence, the Council recommended for clarification in the regulations whether the Act applies to all or to a particular list of genera and species.[561] In this regard, it is to be noted that the presently introduced system in Malaysia is practising the approach of 'open listing', allowing all types of new variety to be registered, but giving priority of protection to 25 types of plant genera and species. The priority list covers few plant categories namely ornamentals, fruits, industrial crops, cereal crop and forest plantation crops.[562] Therefore, in the event that there is an application of a new plant variety which does not fall under the priority list, the processing would be subjected to availability of technical expertise and technical data. This in effect means that the plant variety right office may require a longer period of time to process such application.

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[561] AZMI, *supra,* Note 508, p.2.
[562] The full list of the 'priority list' is available at the DOA's website. Refer <http://pvpbkkt.doa.gov.my>

The following table aptly summarizes the extent of the compliance of Malaysian provision vis-à-vis the UPOV provisions:

Table 4.8

The PNPVA 2004 versus UPOV provision: the extent of compliance

	Particulars	**Malaysian provision (Protection of New Plant Varieties Act 2004)**	**UPOV provisions**	**UPOV-compliant**
1	Conditions for protection	New Distinct Uniform Stable	New Distinct Uniform Stable	yes
2	Scope of protection	(a) Production or reproduction, (b)conditioning for the purposes of propagation (c)offering for sale (d)selling or other marketing (e)exporting (f)importing, and (g)stocking for any of the purposes referred to above	(a) Production or reproduction, (b)conditioning for the purposes of propagation (c)offering for sale (d)selling or other marketing (e)exporting (f)importing, and (g)stocking for any of the purposes referred to above	yes
3	Genera and species	'Open listing', with priority given to a list of crops in accordance with national interest	At least 15 plant genera or species	no
4	Provision on essentially derived varieties	yes	yes	yes
5	Possibility of double protection (that is both under patent and plant breeder's right)	Plant varieties *per se* are specifically excluded from patentability under Patents Act 1983	Possible (UPOV 1991)	yes
6	Researchers' privilege/rights	yes	yes	yes
7	Farmers' privilege/rights	Three special exceptions for small	In the form of an exception in UPOV	yes

		farmers	1991.	
8	Duration of protection	25 years for trees and vines, 20 years for all other plants (with the exception of traditional varieties)	25 years for trees and vines, 20 years for all other plants	yes
9	Compulsory licensing	yes	yes	yes
10	Unique features (*sui generis* approach)	(i)Traditional varieties with lower threshold of registrability ie new, distinct and identifiable (ii) duration of protection is 15 years for traditional varieties	-	no

It has been revealed by the DOA that the effort and steps towards acceding to the UPOV Convention is currently put on hold, as the Government has prioritized the implementation of the Act over the UPOV accession. The Government would like to see the response from the breeders as the Act has just been implemented. The agenda of accession to UPOV has not been totally abandoned yet it is held in abeyance for a period of time which is unascertainable, but it would definitely revive when the need for the accession re-emerges in the near future, or perhaps with the pressure from the UPOV Council or other developed countries.

4.4 The Impediments to the Success of Biotechnology

Despite the existing awareness of the economic potential of the new biotechnology, as well as the concerns in regard to its adverse effects on developing countries, the growth of biotechnology in many Asian countries has remained relatively slow. India, Korea, Malaysia, the Philippines and Thailand have built-up national capabilities in biotechnology to introduce technological advances quickly into production. They would probably be able to increase their share in the global biotechnology harvest.[563] The preceding discussion reveals that Malaysian Government in particular has taken up a number of pro-active steps in order to boost the growth of biotechnology in the country.

(i) Weak scientific critical mass

As far as Malaysia is concerned, there are a number of impediments or problems responsible for the slow growth of biotechnology R&D and the industry in the country. One of the main problems which has been identified is the weak scientific critical mass to set the industry going. On-going and proposed activities to support the growth in the biotechnology industry undoubtedly require a cadre of specifically trained manpower in this field. Malaysia's shortage of skilled labor is most oft-cited impediment to economic growth cited in numerous studies.

In the field of science and technology, Malaysia has an acute shortage of experts and highly qualified professionals, scientists, and academics. The problem is further aggravated by the general decline of the study of life sciences, in terms of the number of students doing undergraduate study in major universities in Malaysia. Figures indicate that in 1998, the number of scientists and engineers per one million population was 500, whereas demand is expected to be 1,000 scientists per one million.[564] A look at the projected output of universities over a 10-year period from 1985, reveals that there will be more arts students than science and technical graduates. The greater

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[563] RIAZUDDIN, S., Country Paper On 'Biotechnology'. Paper presented at *Second Expert Group Meeting On Binasia, Bangkok, January 24-25 2006*. [online], Available at : <URL:http://www.binasia.net/binasiadownload/Pakistan_COUNTRY_PAPER_EGM_Jan06.doc>[Accessed 23 February 2009]

[564] Ministry of Science, Technology & Innovation (MOSTI) Malaysia, *Third Outline Perspective Plan - Developing Malaysia Into A Knowledge-Based Economy*, Available at : <http://www.nitc.my/index.cfm?&menuid=61> [Accessed 01 December 2010].

proportion of graduating students from public education institutions were from the Social Sciences and Humanities. The number of students from the public and private universities graduating in Natural Science and Engineering courses grew in numbers from just 5,588 in 19925 to 12,911 in 2002.[565] Despite this increasing trend, the numbers of science and engineering graduates in Malaysia is still inadequate. To remain competitive, Malaysia has to acquire a large pool of scientists and technologists to meet the challenges and opportunities of the 21st century

(ii) Linkages between the biotechnology industry and the R&D

Another significant impediment is a lack of linkages between the industry and R&D. Some research programs, for example, in the government-based agencies and public universities are designed and pursued without involvement or even a consultation with the local industry. Consequently, support of the private sector is non-existent. This is apparently one of the main problems in developing countries, including Malaysia, where there are laboratory researchers who work in isolation, completely separated from the end-users. There are neither any consultations with the industry to identify the relevance of projects to national needs nor industry participation to take the laboratory research to the end-users. Laboratory research problems are selected to satisfy intellectual appetite rather than to solve specific problems relevance to national needs.

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[565] AHMAD, F., and KRISHNA, V.V., 2006. The Science and Technology System of Malaysia, Available at: <http://portal.unesco.org/education/en/files/55597/11999609765MALAYSIA.pdf/MALAYSIA.pdf> [Accessed 01 December 2010]

(iii) Time factor in patent application

Another oft-cited impediment to the growth of biotechnology R&D and industry in Malaysia is the delay in the processing of patent and trademark registration. The process of registration of these types of IP which is in general a lengthy process, complicated and slow, poses further challenges at the commercialization level of an invention or end-product. In Malaysia, MyIPO is responsible for the development and management of the intellectual property system in Malaysia. At the same time, it is responsible for the implementation of the following Acts; Trade Mark Act 1976, Patent Act 1983, Copyright Act 1987, Industrial Design Act 1996, Layout Designs and Integrated Circuit Act 2000 and the Geographical Indications Act 2000. Prior to 2007, an average patent registration process took 5 to 6 years before a patent could be successfully registered.[566] The delay was mainly because of the patent search process.

(iv) Vagueness in the interpretation of some patent provisions

It has been asserted that there is apparent lack of clarity on the interpretation and examination guidelines on biotech-related inventions. This goes back to the criteria for patentability of an invention, which includes biotech-related inventions. As has been mentioned in the previous discussion, the criteria for patentability of an invention under the Malaysian Patents Act 1983 are that the invention is new, involves an inventive step and has industrial applicability[567], in parallel to Article 27(1) of TRIPS Agreement. From the view of Patent Division MyIPO, the above assertion and perception on a lack of

[566] The data was obtained from Patent Division, MyIPO during the interview session carried out in July 2009.
[567] Section 11 Patents Act 1983.

clarity during the patent examination process is not true. This is based on the premise that the patent examiners generally follow the UK approach in interpreting certain terms or concepts vis-à-vis patentability. The examination process is made clearer and easier with the help of a detailed, comprehensive, official manual of MyIPO namely 'Guidelines For Patent Examination'.[568] For example, a detailed explanation and interpretation is provided for the important terms pertaining to patentability such as 'inventions', 'industrial application', 'novelty', and 'inventive step'.[569]

(a)Lack of clarity in determining the exclusion from patentability

Excluded subject matter[570] includes discoveries, plant or animal varieties or essentially biological processes for the production of plants and animals. However, man-made living microorganisms and microbiological processes, and genetically modified plants that do not amount to a plant variety are patentable.

The excluded subject matter mirrors that prohibited under Article 52 of the EPC. So it is not surprising that MyIPO had an expert from the EPO, advising on the guidelines for the examination of biotechnological patent applications filed in Malaysia. For example, in year 2006, Dr Jürg Bilang, a biotechnology expert from the EPO, undertook a training session for some 25 examiners in the field of biotechnology[571]. The program covered patent examination procedures with particular emphasis on the field of biotechnology, that is patentability of plants and animals, patenting of gene sequences, patentability

568 The manual is available at: < http://www.myipo.gov.my/files/PT_Guidelines.pdf>
569 *Ibid*., refer Chapter IV of the manual.
570 Section 13 Patents Act 1983.
571 Establishment of Biotech Guidelines & Training of Examiners, 27 February – 10 March 2006, Kuala Lumpur.

of 3D structures. He also assisted MyIPO in drafting guidelines on search and examination in the field of biotechnology.

MyIPO's guidelines follow closely, if they are not identical to, the EU Directive 98/44/EC on the legal protection of biotechnological inventions. In fact, MyIPO has set up a joint committee to formulate a policy for patenting biotechnological inventions in Malaysia. The MyIPO's official guidelines for the examination of biotechnological patent applications will be finalized and is expected to be published after Malaysia becomes a member of the Budapest Treaty for the deposit of microorganisms and other biological materials for the patent procedure.

(b) Problems in ascertaining 'inventive step'

As far as patentability of an invention is concerned, another oft-cited challenge is the threshold of the requirements, which encompasses the interpretation of 'inventive step' and 'industrial application'. Contrary to the perceived lack of clarity in the interpretation, the Patent Division of MyIPO firmly maintains that these terms are clearly interpreted in the official MyIPO Patent Manual, hence there is no vagueness in the interpretation.[572] In this regard, the term 'inventive step' is defined in the manual under Chapter IV, Rule 10.1 as:

'An invention shall be considered as involving an inventive step if, having regard to any matter which forms part of the prior art…such inventive step would not have been obvious to a person having ordinary skill in the art.'

It is further elaborated under the rule that novelty and inventive step are two different criteria, in the sense that novelty exists if there is any real difference

[572] *Supra*, Note 511.

between the invention and the known art, while the question of inventiveness only arises if there is novelty. While the claim should in each case be directed to technical features and not merely to an idea, in order to assess whether an inventive step is present, there are various ways in which an invention may be arrived at. One typical example as provided in Rule 10.5 of the manual is that an invention may be based on the devising of a solution to a known problem; for example, the problem of permanently marking farm animals such as cows without causing pain to the animals or damage to the hide has existed since farming began. The solution ("freeze-branding") consists in applying the discovery that the hide can be permanently depigmented by freezing.

In short, Rule 10 (which contains eight sub-rules) of the patent manual as a whole serves as a useful and comprehensive guide to the patent examiners in assessing the criteria of 'inventive step', thus rules out any oft-cited perception of lack of clarity in the interpretation of this particular term and concept.

(c) Problems in determining 'industrial application'

Another term worth discussing vis-à-vis patentability is 'industrial application' in relation to biotech patent. Since MyIPO is closely following the approach of the UK and EPO, it is interesting to highlight the recent development of judicial interpretation of this term. The UK court, in considering the industrial application of biotech patent claims, rules that speculative uses for a protein are not sufficient to fulfill the requirement of industrial application since a patent is not a 'hunting licence' to find a use for an invention.[573] In relation to

[573] *Eli Lilly and Company v Human Genome Sciences, Inc* [2008] EWHC 1903 (Pat), Kitchin J, 31 July 2008.

the MyIPO patent manual, Rule 5 which is provided for Section 16 Patents Act 1983 defines the term 'industry' as to be understood in its broad sense. This includes any physical activity of 'technical character' namely an activity which belongs to the useful or practical arts as distinct from the purely intellectual or aesthetic arts.

In this regard, it is noteworthy that 'industrial application' does not necessarily imply the use of a machine or the manufacture of an article, hence it could also cover a process for dispersing fog, or a process for converting energy from one form to another. The manual also mentions another example, namely, methods of testing, which is interestingly regarded as inventions susceptible of industrial application and therefore patentable. All the examples as incorporated in the manual reflects the 'actual' (as opposed to the 'speculative') industrial application. The Patent Division of MyIPO confirms[574] that during the patent examination processes, the patent examiners substantially rely on the title, abstract and description of a patent application, and this includes the compliance with the requirement of industrial application.

(v) Issue on commercialization

Other than the above impediments, the slow growth of biotechnology R&D and industry is also attributed to the fact of underdeveloped IP asset management from the point of discovery to the point of commercialization of the biotechnological products. Typically, commercialization of new IP is enabled via partnerships with established business firms. However, establishing licensing agreements with existing industrial players does not maximize the commercial potential of the innovation. This is a common scenario in Malaysia,

[574] *Supra*, Note 511.

especially when dealing with breakthrough technologies arising from basic research, for instance from university's research. In this regard, the proposed strategy and best practice will consist in initiating strategic partnerships with the industrial and financial sectors to ensure the successful commercial exploitation of the innovations transferred by the universities and research institutions.

The commercialization rate of publicly funded research in Malaysia is still low. Typically, the low rate of commercialization of R&D findings is attributed to facts such as the lack of funding mechanisms for research, unawareness or lack of concern among the researchers about the commercial potential of their findings, research focus which is only limited to publications rather than a culture of commercializing research products and paucity of networking mechanisms to link key parties necessary in commercializing research findings.[575]

(vi) Low percentage of global players

As far as the Malaysian situation is concerned, another problem which has been identified is a lack of indigenous global players[576] which have the capacity and capability to contribute to the growth of local biotechnology industry. The situation is further aggravated by the fact that there is a very limited number of world class companies that are willing to venture or invest

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[575] These factors are the findings from the National Survey of Public Research Commercialization in 2003 under Malaysia Ministry of Science and Innovation (MOSTI). Refer : <http://www.slideshare.net/CAS.IP/licensing-of-modified-virgin-coconut-oil-in-malaysia-3585197> [Accessed 08 September 2010]

[576] For example, one of the prominent local global players is Sime Darby Berhad <http://www.simedarby.com/>

in the country. A biotechnology proponent says there are few significant biotech foreign investments in Malaysia.[577]

4.4.1 Some efforts in tackling the impediments

The Government and relevant bodies such as BiotechCorp and MyIPO are fully aware of the impediments to the successful growth of the biotechnology industry in Malaysia. In order to improve this situation, the Government took the initiative to establish 'the Special Taskforce to Facilitate Business' or PEMUDAH (taken from the taskforce's Malay name '*Pasukan Petugas Khas Pemudahcara Perniagaan*') on 7th February 2007.[578] Approval has since been given for MyIPO to engage additional staff for the purpose of patent examination. With the additional staff, as at 31 December 2007, MyIPO had cleared the backlog going back to October 2004. MyIPO aims to clear the backlog and reduce duration of registration to 3 – 4 years, hence improving the current average process of four and half years to five years.

On top of the abovementioned initiative, MyIPO and BiotechCorp have ventured into a joint project, namely 'The Patent Examiner Outsourcing Program' with the aim to resolve the current patent examination backlog and enhance the ability of MyIPO to grant biotechnology patents within a shorter period of time. By end of the year 2007, a total of four biotech patents examiners were sent on a short-term attachment at the Australian patent office to be trained under experienced Australian patent examiners. 'The International Exchange Programme for Patent Examiners' is another joint

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[577] NGUI, Clarence Y.K., 2005. Continuing the biotech challenge, *Malaysian Business*, Available at: <http://findarticles.com/p/articles/mi_qn6207/is_20051101/ai_n24909340> [Accessed 26 February 2009]

[578] Refer <http://www.pemudah.gov.my/info>

MyIPO-BiotechCorp project to enhance the proficiency of Malaysian biotech patent examiners as well as to foster strategic ties with IP Offices identified to be at the leading edge of the industry. MyIPO-BiotechCorp secured agreements from both the European and Korean Patent Offices where each patent office have hosted for Malaysian patent examiners for attachment and training in 2007.[579]

The drafting of MyIPO official guidelines for the examination of patent applications is another positive effort which is very much anticipated by the biotechnology industry. The Guidelines are hoped to clear the apparent vagueness on the interpretation of some related terms with regard to biotechnological inventions, in particular plant biotechnology.

4.5 Conclusion & Contribution

In short, while Malaysia has identified biotechnology and agriculture as key economic drivers, commercialization of local grown technology is in its infancy. Scientists are struggling to translate their bench work into dollars and cents, whereas the local entrepreneurs and industry are not in the forefront yet to invest and buy technologies from public research institutes and universities. Hence, there is a real need for all those involved in this industry to rise to the challenges and impediments in order to enhance the growth in the Malaysian scenario of biotechnology in general and the agricultural biotechnology in particular. After all, as highlighted in the preceding discussion, Malaysia has all the vital ingredients to succeed in the biotechnology sector, namely, proper policy, clear direction, sound implementation as well as infrastructure, yet it needs to improve on its critical mass and to ensure sufficiently trained human

[579] *Supra*, Note 489, at p.30.

resources to meet the requirement along the value chain of each biotech product, from R&D right through commercialization to prevent unwarranted delay.

Chapter 5

The Views of Malaysian Plant Breeders

5.1 Introduction

The Malaysian biotech industry is dominated by small-to-medium sized companies with a handful of larger players, such as those running plantations, which have developed strong R&D arms within their corporations.[580] As far as research activities are concerned, biotechnology research in Malaysia is mainly undertaken by public sector institutions such as MARDI, MPOB, MRB, FRIM, MCB and the like. Having said that, it is pertinent to note that the private sector's involvement in agricultural biotechnology is primarily focused on plant tissue and cell culture. This ranges from the production of ornamental plants such as orchids and pitcher plants, herbal plants which have medicinal uses, to mass-propagated top-of-the line plants.

The focus of this chapter is on the analysis of the data which has been collected via semi-structured interviews with a number of public sector research institutions. The results of the interviews are important, as the selected research institutions represent a large component of the views of plant breeders in Malaysia. The questions for the semi-structured interview were carefully drafted with the main aim to assess *inter alia* the extent of use, awareness, appropriateness and effectiveness of the existing legal protection vis-à-vis IPRs available to those involved in agricultural biotechnology. The response to the interview was to some extent an indicative of the views of those involved in the industry and R&D of agricultural biotechnology. In

[580] An excellent example of a large player is Sime Darby Berhad, whose operations span across 20 countries and is supported by a team of over 100,000 people worldwide. <http:// http://www.simedarby.com/Corporate_Profile.aspx>

addition, the interviews seek to identify those areas where further legislative activity might be needed.

5.2 Brief background of the research institutes and agencies

For the purpose of this research, the following agencies and research institutions were selected as the respondents for the semi-structured interviews:

1) MARDI (The Malaysian Agricultural Research and Development Institute)
2) FRIM (The Forest Research Institute Malaysia)
3) MPOB (The Malaysian Palm Oil Board)
4) MRB (The Malaysian Rubber Board)
5) MCB (The Malaysian Cocoa Board)

The selection of the above respondents was justified on the basis that the main industrial crops in Malaysia are oil palm, rubber and cocoa, of which the research work is undertaken by MPOB, MRB and MCB respectively, whereas the research activities for other types of plants such as rice, banana, coconut, papaya and so forth are entrusted to MARDI.

On top of the above five agencies and research institutions, general interviews on the topic of agricultural biotechnology, patents and plant breeders rights' as well as visits for the purpose of data collection[581] were also carried out at these bodies:

1) BiotechCorp (Malaysian Biotechnology Corporation)
2) MOSTI (The Ministry of Science, Technology and Innovation)

[581] Some of the data and information obtained has been incorporated in the discussion in the preceding Chapter of this thesis.

3) Crop Quality Control Division, Department of Agriculture (DOA)

4) Patent Division, Intellectual Property Corporation of Malaysia (MyIPO)

In fact, these bodies and agencies play the role of regulators and facilitators to the matters and issues related to biotechnology and IPRs in Malaysia.

5.2.1 MARDI

MARDI was established in the 1970s with the main objective of generating and promoting new, appropriate and efficient technologies towards the advancement of the food, agriculture, food and agro-based industries. One of the MARDI's vital functions is conducting research in the fields of science, technology, economics, and society with regard to production, utilization and processing of all crops (except rubber, oil palm and cocoa), livestock and food. Since agricultural biotechnology has been identified as one of the key technologies needed for transforming and modernizing agriculture, MARDI has expertise in many areas of agricultural biotechnology such as molecular biology, genetic engineering, diagnostics, bioreactor technology and biosafety. The expertise in these areas could generate state of the art technology in the agriculture sector.[582]

MARDI research teams focus on various crops, which include rice and papaya. MARDI has been successful in producing and establishing the transformation system for local rice varieties. Transgenic rice containing the coat-protein gene for the *tungro* virus has been developed, and glasshouse screening has been completed. Transgenic rice with herbicide resistance has also been produced and is currently in glasshouse trials. Other than rice, work on gene cloning for papaya ringspot virus coat protein gene and the ethylene gene ACC oxidase

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[582] Refer <http://www.mardi.my>

for improved shelf-life started concurrently with the development of the transformation system for papaya. Now transgenic papaya containing the shelf-life gene are being produced and analyzed.[583] A local variety of papaya resistant to ring spot virus will be a boost to local farmers as it poses a big problem to them especially in the southern parts of Peninsular Malaysia. This will increase the yield and improve the quality of their produce, while protecting the plants from the virus.

5.2.2 FRIM

FRIM was founded in 1929, and is currently one of the leading institutions in tropical forestry research, both within Malaysia and abroad. FRIM is primarily responsible for the planning and implementing of research for the development of the forestry sector and conservation of forest resources in Malaysia. The biotechnology-related research activities are under the Forest Biotechnology Division of FRIM, which is involved in creating new planting material through genetic engineering. The functions of the Division include seed testing, seed storage facilities, DNA sequencing and so forth.[584]

5.2.3 MPOB

Malaysia currently accounts for 39% of world palm oil production and 44% of world exports.[585] Being one of the biggest producers and exporters of palm oil and palm oil products, Malaysia has an important role to play in fulfilling the growing global need for oils and fats sustainably. In this regard, MPOB, the premier government agency, has been entrusted to serve the country's oil

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[583] The project is part of the Papaya Biotechnology Network of Southeast Asia initiated by the International Service for the Acquisition of Agri-Biotech Applications (ISAAAA).
[584] Refer <http://www.frim.gov.my>
[585] Refer : <http://www.mpoc.org.my/Malaysian_Palm_Oil_Industry.aspx> [Accessed 31st August 2010]

palm industry. Research and development is the thrust of MPOB's activities, ranging from upstream production to downstream processing which is carried out by the various research divisions. The research activities are aimed at maximizing productivity, improving production efficiency and quality, and increasing value creation by expanding the palm oil and palm kernel oil value chain to promote a globally competitive and sustainable industry.

MPOB plays a significant role in applying and promoting oil palm biotechnology, notably research relating to crop production and management as well as advanced biotechnology, which include breeding and genetics and tissue culture.[586]

5.2.4 MRB

The Malaysian Rubber Board (MRB) is the custodian of the rubber industry in Malaysia. MRB has contributed significantly to the development of the rubber industry for the last 78 years. The R&D excellence in natural rubber, accomplished by the Rubber Research Institute of Malaysia (RRIM) which is now under MRB, has had an impact on the Malaysian natural rubber industry and other natural rubber producing countries.

The primary objective of MRB is to assist in the development and modernization of the Malaysian rubber industry in all aspects from cultivation of the rubber tree, the extraction and processing of its raw rubber, the manufacture of rubber products and the marketing of rubber and rubber products.

[586] Refer : <http://www.mpob.gov.my>

Research undertaken in the Biotechnology Unit covers the areas of tissue culture and genetic transformation aiming at the enhancement of crop productivity by improving selected agronomic traits of the rubber tree, molecular markers and genetics, plant physiology, biochemistry and molecular biology, reproductive biology and latex allergy. While these areas encompass the basic and strategic biological research activities undertaken on *Hevea brasiliensis*,[587] a significant portion of the unit's research has been structured to address specific needs of the rubber industry.[588]

5.2.5 MCB

The Malaysian Cocoa Board (MCB) was established in 1988 with the main objective of developing the cocoa industry in Malaysia to be well integrated and competitive in the global market. Emphasis is given to increasing productivity and efficiency in cocoa bean production and increasing downstream activities.

A specific centre under the MCB, that is, COCOABiotech Centre of Excellence was established in 2002. This centre aims to implement research and development cocoa biotechnology program of innovation and application. Some of the important achievements in agro-biotechnology include molecular fingerprinting of cocoa clones, molecular markers for selection of shorter cocoa trees, development of cocoa trees resistant to pod borer and so forth.[589]

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[587] Latin name for rubber tree from which the largest volumes of latex are harvested for use in the manufacture of natural rubber
[588] Refer : < http://www.lgm.gov.my>
[589] Refer : <http:www.koko.gov.my>

5.2.6 BiotechCorp

BiotechCorp was established in 2005 with the aim of nurturing and accelerating growth of Malaysian biotechnology companies, as well as to create a conducive environment for biotechnology.

As far as agricultural biotechnology is concerned, BiotechCorp continues to take pro-active steps towards developing a more vibrant agriculture sector by facilitating the establishment of several commercial entities involved in key areas of agricultural biotechnology in the country such as in agricultural genomics, production of planting materials through tissue culture technology and production of bio-pesticides and bio-fertilizers for plant protection and nutrition. As at 31st December 2008, 31 agricultural biotechnology companies under Industry Development Division (Agriculture) have been awarded Bionexus status,[590] which is a kind of recognition awarded by the Malaysian government through BiotechCorp to qualified companies that participate in and undertake value-added biotechnology businesses.

5.2.7 MOSTI

The Ministry of Science, Technology and Innovation provides assistance to those with the expertise and resources to carry out biotech-driven R&D and to develop businesses in the sector, especially in the priority areas such as agriculture. National Biotechnology Division (BIOTEK) under MOSTI is a part of MOSTI's biotechnology cluster to harness the full potential of biotechnology in the new economy. Since its establishment in 1995, BIOTEK has consistently

[590] BiotechCorp Final 2008 Annual Report, Available at : <http://www.biotechcorp.com.my/pdf/Final%202008%20Annual%20Report.pdf>

been involved in R&D, technology development and biotechnology awareness programs.

The pivotal role of BIOTEK is managing and facilitating funding for those with the expertise to carry out research on platform technologies. Besides, BIOTEK embarks on technology transfer, files patents, sets up good laboratory practice facilities and forms bio-informatics networking.[591]

5.2.8 Crop Quality Control Divison, Department of Agriculture

The Department of Agriculture (DOA) has been registering fruit clones since the early 1930's and was officially authorized as the National Registrar of Varieties in 1994 by the Ministry of Agriculture. The responsibility in implementing the PNPV Act 2004 has been entrusted to the DOA. Presently, there are 45 crop examiners nationwide who work for research institutes and government agencies, including 16 examiners who work for DOA. The New Plant Varieties Test Center was established in year 2008, with facilities such as fields and greenhouse for conducting growing tests.

The 2008 Regulations[592] were gazetted on 20th October 2008, hence the Crop Quality Control Division which acts as the Malaysian PVP office has been accepting applications for registration of new variety as from the abovementioned date. The cumulative number of applications now has reached 54.[593]

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[591] Refer : <http:www.mosti.gov.my>; MALAYSIA. Ministry of Science, Technology and Innovation, 2007. *National Biotechnology Division – Biotechnology for Wealth Creation, Societal and Nation Well-being*. Putrajaya: BIOTEK Malaysia.
[592] Protection of New Plant Varieties Regulations 2008.
[593] As at September 2010, source : <http://pvpbkkt.doa.gov.my/>

5.2.9 Patent Division, MyIPO

Intellectual Property Corporation of Malaysia was established with the main objectives of establishing a strong and effective administration as well as strengthening intellectual property laws in Malaysia. The Patent Division of MyIPO has three subdivisions in terms of its examination functions, that is patent formality section, engineering and applied science. In this regard, patent applications of agricultural biotechnological inventions fall under the responsibility of the applied science division.

5.3 Assessing the Views of Malaysian Plant Breeders

5.3.1 Biotechnology research activities: The current status and focus

Genetic modification research in Malaysia mainly involves crop improvement work, especially in relation to developing pest and disease tolerant crop varieties, high-yielding and value added crop varieties. To date, there is no record of a commercial variety being released for commercial planting that has been genetically modified using recombinant DNA technology.[594] In Malaysia, there are several commercial crops being studied or being modified genetically, for example papaya, rice, and chilli by MARDI, oil-palm by MPOB, cocoa by MCB, rubber tree by MRB and teak by FRIM.

It is of paramount importance to ascertain and identify the types of biotechnology research undertaken by the RIs and relevant bodies, as it would be indicative and reflective of the research trends in Malaysia. The relevant question to be answered is whether R&D in those RIs is focusing on 'gene' from its very basic stage, or whether the RIs research teams are merely

[594] Refer : Biotechnology Information Centre (MABIC) <http://www.bic.org.my/?action=localscenario&do=legislation> [Accessed 01 December 2010]

replicating and applying the current available biotechnology in plant biotech worldwide. It was discovered based on the interviews[595] and various online sources[596] that generally, most research activities in those RIs focus on genetic engineering for crop improvement, disease and herbicide resistance and value added products. In this regard, some of the technologies used are inevitably based on existing plant biotechnology which has been proven a success in the industrialized countries such in the U.S. and Europe.

One relevant example would be the application of *Bacillus thuringiensis* (*Bt*) transgenic technology to various plants in Malaysia, such as rice, papaya, sweet potato and the like. The research is on-going, hence it remains to be proven whether *Bt*-transgenic technology would work and be effective for other types of crops than corn and cotton.[597] On the global stage, the majority of commercially released transgenic plants are currently limited to plants that have introduced resistance to insect pests and herbicides. Insect resistance is achieved through incorporation of a gene from *Bt* that encodes a protein that is toxic to some insects. For example, if the cotton bollworm, a common cotton pest, feeds on *Bt*-cotton it will ingest the toxin and die. Herbicides usually work by binding to certain plant enzymes and inhibiting their action. The enzymes that the herbicide inhibits are known as the herbicides target site. Herbicide resistance can be engineered into crops by expressing a version of target site protein that is not inhibited by the herbicide. This is the method

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[595] The various semi-structured interviews with selected RIs and relevant bodies were carried out in June- August 2008, and in August 2009.

[596] All RIs have their own website, detailing their research focus and R&D activities. MARDI : <http://www.mardi.my>; MPOB: <http://www.mpob.gov.my>; MRB: <http://www.lgm.gov.my>; FRIM: <http://www.frim.gov.my>; MCB: <http://www.koko.gov.my>.

[597] Ironically, scientists from India, China and the United States have discovered that Bt crops ie genetically engineered with *Bt* toxin proteins from the soil bacterium *Bacillus thuringiensis* targeted at insect pests, often failed to protect against pest attacks, and have other problems as well. Refer :< http://www.i-sis.org.uk/SCFOBTC.php> [Accessed 23rd August 2010].

used to produce *glyphosate* resistant crop plants. In this regard, insect-protected plants containing a natural insecticide protein from *Bt* (for example *Bt*-cotton and *Bt*-corn) have successfully provided millions of farmers worldwide with increased yields, reduced insecticide costs and fewer health risks. Hence, it is not surprising for a developing country such as Malaysia to apply similar technology in order to enhance specific plants for the benefit of local farmers and consumers. At this juncture, it is worth noting public RIs in Malaysia are actively researching the application of *Bt*-transgenic technology for target plants and crops, for instance, disease and herbicide resistant varieties in rice and cassava as undertaken by MARDI's research team.

The research emphasis[598] of respective RIs is summarized in the following table.

Table 5.1

The area of research emphasis of major RIs in Malaysia

RIs	Research Emphasis
Malaysian Agricultural Research and Development Institute (MARDI)	(i)Delayed ripening in papaya (ii)Disease resistance in rice, chilli, papaya and sweet potato (iii)Floral colour in orchids (iv)Improved quality and nutrition in rice, cassava and sweet corn (v)Yield improvement and herbicide resistance in rice
Malaysian Palm Oil Board (MPOB)	(i)Yield improvement (ii)Improved oil quality (iii)Production of biodiesel (iv)Research on oil palm genomes
Malaysia Rubber Board (MRB)	(i)Disease resistance (ii)Production of high-value protein

598 The information is based on the data collected from the semi-structured interview sessions and respective RI's websites.

Malaysian Cocoa Board (MCB)	(i)Disease resistance (ii)Yield improvement (iii)Production of specialty cocoa trees
Forest Research Institute of Malaysia(FRIM)	(i)Delayed flowering and disease resistance in teak

The knowledge and understanding of the current nature, research focus and R&D activities undertaken and carried out by those RIs in Malaysia is vital to ascertain the suitable, best IP protection for the R&D yields and output. This is because plant breeders, researchers and investors in Malaysia presently have the option under patent laws or plant variety rights; either or both types of protection that best suit their needs to protect their inventions.

5.3.2 The significance of agricultural biotechnology R&D activities

All research institutes which play significant roles in agricultural biotechnology R&D in Malaysia have their own specific unit or division to run their biotechnology research activities. This is parallel to the Government's aspiration and mission to boost the local biotechnology sector. In fact, effective R&D is one of the Government's primary initiatives towards harvesting the potential of biotechnology as a growing source of the country's wealth creation.

The RIs like MARDI, MRB and MCB are backed by Government funding and budget allocation to maintain their operation and R&D, whereas MPOB derives its funding mainly from cess[599] imposed on the industry for every tonne of palm oil and palm kernel oil produced. Nevertheless, in addition, MPOB receives budget allocations from the government to fund development projects

[599] Tax imposed on palm oil producer, that is at the rate of RM9 per tonne of palm oil and palm kernel oil produced at the mills and crushers (as at December 2008); Refer : <http: //www.palmoilhq.com>

and for approved research projects under the Intensification of Research in Priority Areas (IRPA) programme.[600] MRB similarly imposes cess[601] on natural rubber production as part of its funding sources, other than the budget allocations from the Government.

It is essential to ascertain the sources of funding of the RIs as it would affect and shape their R&D activities on a wider perspective. The relevant discussion on this matter follows in the latter part of this chapter.

The following table summarizes the finding of the semi-structured interviews with regard to the data on biotech-related R&D of the RIs:

Table 5.2

The summary of finding collected during the semi-structured interview

Research Institutes / Organization (RIs)	Years of involvement in biotechnology	Percentage of employees involved in biotech R&D	Percentage of financial resources for biotech R&D	Plant species
MARDI	20	> 50	NA	All crops except palm oil, rubber, cocoa
MPOB	40	20	NA	palm oil
MRB	20	15	>10	rubber
MCB	9	15	>10	cocoa

[600] *Supra*, note 486.
[601] A cess at the rate of 3.85 cents shall be imposed on every kilogramme of natural rubber exported from Peninsular Malaysia. (Order 2(1) of Malaysian Rubber Board (Cess) Order 2000 under Malaysian Rubber Board (Incorporation) Act 1996).

FRIM	10	10	10	Forestry (acacia, teak, rattan, bamboo etc) herbs

All RIs interviewed have their own specific unit or division dealing with research in agricultural biotechnology. Being RIs, all of them have been involved in biotechnology research since their establishment; this is very true as the term biotechnology in general encompasses both 'conventional' and 'modern' biotechnological revolution. After all, their long research involvement in agricultural biotechnology is not surprising as it is one of the most promising developments in modern science, in addition to the fact that Malaysia is well endowed with natural resources in agriculture.

Research in agricultural biotechnology as being undertaken by these RIs revolves around the genetic improvement of industrial crops and plant varieties, agricultural genomics, as well as tissue culture technology in transgenic crops and forest trees.[602] There are in fact a number of ongoing researches on genetically modified plants but all are still at the experimental stage, as confirmed by MARDI. Other key research areas for the agriculture sector include livestock farming, animal health and nutrition, bio-pesticides and bio-fertilizers, extraction of metabolites and nutritionally enhanced agriculture products.

The significance of biotechnology research is represented in the percentage of the employees and researchers involved in the research, as well as the

[602] The fact is confirmed by the RIs during the semi-structured interviews as carried out in 2008.

funding or budget allocation for such activities as shown in Table 5.1. The percentage of employees committed to agricultural biotechnological research in the RIs ranges from 10 to 50 percent, evidencing the growing importance and prominence of biotechnological industry in Malaysia. In relation to this, the Government of Malaysia in its Ninth Malaysia Plan allocates a total of RM 2,021.3 million funding for biotechnology sector.[603]

5.3.3 Patenting Activities

Biotechnology is a product of human efforts and innovation and can only develop in a condition with solid scientific and technological background. The response from the RIs and government agencies during the semi-structured interview sessions reveals that patenting activities have been an important part of their integrated role in R&D. The following table essentially summarizes their patenting work.

Table 5.3

Statistic of patenting activities by major RIs in Malaysia

Research Institutes / Organization (RIs)	The year in which first Malaysian patent application made	Number of current patents (year 2008)	Patents abroad	Number of patents applied annually	Average number of patents granted annually
MARDI	1996	Approved/granted: 3 Filed/Pending: 15	No	5-8	3
MPOB	1980s	Approved/granted: 60 Filed/Pending: 150	Yes	18-20	3
MRB	1934 (first patent applied)	Approved/granted: 119 Filed/pending: 16	Yes	4	2
MCB	2004	Approved/granted: 5 Filed/pending: Not available	Yes	1	1
FRIM	1990	Approved/granted: 19 Filed/pending: 19	Yes	4	2

603 Source : 9th Malaysia Plan, Economic Planning Unit.

It is interesting to note that applying for patents seem to be an obligation undertaken by these RIs and agencies. After all, it has become a trend nowadays as patent applications provide a good indicator of technological innovation and capacity performance of an institution or body. It is clear from Table 5.2 that patenting activities in these research institutions have taken place as early as 1934, that is when MRB applied for its first patent.[604] However, as far R&D in local biotechnology is concerned, patenting works has started to gain momentum in 1980s and 1990s.

MRB for instance started its work on genetic transformation of rubber cells in the year 1990. In fact MRB has been very active in their biotechnology research, focusing *inter alia*, on the transgenic rubber tree research with the aim of improving rubber tree productivity. The transgenic rubber tree stands to gain a wide variety of desirable agronomic traits. High latex and timber yield are some of the areas that the rubber industry stands to gain and to serve the latex based sectors and the wood based industries.

Based on the figures in the Table 5.2, it is very clear that MPOB has been the most active institution in patenting activities. It has 60 approved patents, while 150 applications are still pending.[605] As a matter of fact, MPOB plays a significant role in applying and promoting oil palm biotechnology in Malaysia[606]. It is one of the most productive agencies in producing technology

[604] The patent was concerning the improvements relating to the treatment of rubber latex. Source : <http://www.lgm.gov.my/general/NRHistory.aspx> [Accessed 19 January 2010]

[605] The figure is correct as at Jun 2008, obtained during the semi-structured interview sessions with MPOB official.

[606] Privately-owned corporation which is also focusing on oil palm research in Malaysia is Sime Darby. It has recently reported its success on oil palm genome research which is instrumental to boost palm oil yields, better planting materials and generation of new variety of crops. Refer : <http://biz.thestar.com.my/news/story.asp?file=/2009/5/14/business/3896765&sec=business> [Accessed 08 September 2010]

and new innovations which contribute directly to the palm oil industry. The large number of patents held and applied by MPOB is attributed to the fact that it works directly for the industry players in the local palm oil industry, and their funding operation and revenue is mainly generated from cess collection of palm oil and palm kernel oil produced at the mills and crushers. In addition, MPOB receives budget allocations from the government to fund development projects and for approved research projects. Having said that, MPOB is obviously very active and has shown a strong commitment in its research and development, and this goes parallel with their patenting activities. Interestingly, filing of patent had been a culture for MPOB since the introduction of its IP policy in 1999.[607]

Other than MPOB, MARDI is another important RI in Malaysia, which has been very active it its research activities ever since its establishment in 1971. Nevertheless, most of its research outputs remain in the laboratory as they have not been patented nor commercialized. As far as patent applications are concerned, patenting activities in MARDI has started to gain pace in 1996. MARDI has since been moving gradually from a pure focus on research activities towards a more active approach in terms of patents and commercialization. In fact, MARDI has set up certain targets in terms of achieving its number of patents filed and granted, which is set around 5 to 8 patents annually.

Nevertheless, MARDI has yet to file or hold any patents abroad. This is attributable to the fact that it sees no necessity yet to file international patents

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[607] Refer : <http://palmnews.mpob.gov.my/palmnewsdetails/palmnewsdetail.php?idnews=3072> [Accessed 08 September 2010]

to protect their research results, which revolve around new food cops varieties and clones. One of the underlying reasons is the financial factor, as patenting abroad would incur a high cost. As far as patenting is concerned, MARDI has put in a total of 14 patent applications over 10 years (1996-2006).[608] The number is minimal, yet it reflects a positive development and progress in protecting its research via IPRs notably patents.

It is worth noting in comparison to MPOB and MRB who work directly for the industry players and hence very efficacious in patenting their inventions, MARDI is much less aggressive in its patenting activities as there is a lack of takers or investors for its research outputs and inventions. This is further attributed to the fact that most local agriculture-based manufacturers are small and medium-sized companies, with limited financial resources and funding to commercialize MARDI's inventions.

FRIM equally shows an active participation in protecting its inventions via patents, and currently holds 29 patents.[609] As one of the world reputed centres for tropical forestry research, FRIM has more than 100 years of experience in forestry and forest products research. Their patenting activities started in 1990, with a total of 19 patents held currently,[610] though its annual number of patents filed remains minimal. Being one of the twelve mega-diversity countries in the world, FRIM has a very significant role in agro-forestry and biotechnology, researching into plants and forest produces. Some of the plants

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[608] The figure is based on a report in a newspaper, which is available at : <http:// www.bic.org.my/BICalert/0107/080107NST-0.pdf>[Accessed 19 January 2010]
[609] As at June 2008.
[610] Source : <http://www.frim.gov.my/commerlization2.cfm> [Accessed 19 January 2010]

which are being actively researched into at FRIM include rattan, bamboo, *Eurycoma* herbs and teak.

MCB currently owns 5 patents, targeting a minimum of one patent application to be filed annually. Malaysia is Asia's largest cocoa grinder in terms of capacity and volume hence MCB was established in 2004 to focus its research exclusively on the cocoa bean plant. The role played by MCB is important to the development of the cocoa industry in Malaysia to be well integrated and competitive in the global market ultimately. MCB's current biotechnology research in cocoa biotechnology is inevitable to create higher yielding cocoa hybrids in order to assist cocoa farmers to produce more of this precious commodity.

In short, patenting activities that have been taking place in the major RIs in Malaysia to some extent serve as a positive indicator, signifying the increased awareness of IPRs among local breeders to protect their products of research and development. After all, any research in agricultural biotechnology projects is expensive, attracting a large amount of investment and financial resources, as well as being hugely time-consuming. Having said that, IP protection via the patent regime is seen as one of the strongest, justifiable protections for the biotechnological inventions, which include agricultural biotechnology.

At this juncture, it is worth noting that as far as Malaysian scenario is concerned, there remains some assertion and perception from general public and NGO's that the products of research and development by research institutions should be freely available as a large portion of the funding comes from the Government. This argument could be met by the fact that even the

Government in the long run being the financier and investor would expect a return of investment and making profits or at least to cover the research cost. This is in addition to providing the researchers involved in the research project the extra monetary initiatives and driving force in their research efforts and endeavours.

To recap, based on the data and figures obtained during the semi-structured interviews, it is clear that patenting activities among Malaysian local breeders have started to gain pace and popularity and it is not surprising that they would become trends in the near future, in line with the view that strong patent protection would stimulate further innovation.

5.3.4 Issues on Patents

5.3.4.1 Problems in Patents Application

As has been mentioned in the early part of this thesis, the Malaysian patent legislation consists of an interesting mix of provisions adopted from UK patent laws, with some uniquely national features. Hence, the RIs and agencies admitted that there are some common, typical problems inherent in the Malaysian patent law systems.

MARDI's officials were of the view that patent applications in Malaysia are quite costly. In this regard, MCB shared the same view with MARDI in highlighting the high cost[611] for a patent application in Malaysia. This is

[611] On average, a lawyer's fee for drafting a patent description would be between RM5000 and RM10,000. To get an invention patented, a rough estimate of the cost is between RM8,000 to RM9,000. This is however excluding professional translation fees. The total cost however may go up to RM 40, 000 depending the various types of patents. Source : Shearn Delamore & Co, as reported in the newspaper, available at : < http:// www.bic.org.my/BICalert/0107/080107NST-0.pdf>[Accessed 19 January 2010]

aggravated by the difficulties in finding a qualified and skilful patent agent specialized in agricultural biotechnology. MPOB on the other hand highlighted other problems such as time-factor, as a patent application is time-consuming, right from the time it is filed until the final stage when the patent is granted. Another problem is lack of skills on the part of local patent agents in drafting patent application in the areas of biotechnological patent inventions. Interestingly, MOPB encountered no problem in applying for patents abroad, provided the patent application at the national phase is successful.

MRB and FRIM seem to share the same view with MPOB, stating that the time-frames are a challenge in a patent applications. In the event that an application requires for further amendment, the whole process would be much longer in time and overall it is really time-consuming before a grant of a patent could take place.

It is important to note at this juncture that the problems of time-frame and 'time-consuming' in patent applications are in fact inherent and inevitable. In other words, delays in the patent granting process is a common problem faced by Malaysia. This is actually based on the patent legislation and system itself. In Malaysia, the average time to obtain a patent ranges from twelve to thirty months from PCT national phase entry, and from forty-two to sixty months from priority date for Paris Convention applications. After all, all Malaysian patent applications are subject to substantive examination, which is very time-consuming. The current examination system relies extensively on the results of search and examination of the same invention in certain recognized jurisdictions, which include patent offices of Australia, UK, Japan, Korea, the US and the EPO.[612]

5.3.4.2 Patents in Agricultural Biotechnology

As the pace of scientific discovery in agricultural biotechnology has accelerated over the past few decades, the use of patents and other IRRs to protect the inventions and techniques applicable to plant breeding and seed technology has increased tremendously, particularly in developed countries such as the US and European countries.

In this regard, RIs and agencies which are directly involved in the R&D of agricultural biotechnology play vital roles in realizing the country's aspiration and vision to become one of the global players in biotechnology. Therefore, Malaysia is committed to providing a strong IP protection regime under the Biotechnology Policy. As far as patent is concerned, MPOB is the leader in patenting its research outputs relating to agricultural biotechnology. MPOB has a total of 6 patents which directly relate to protect techniques applicable to plant breeding technology, namely palm oil. Interestingly, it has also applied for and been granted patents in countries such as Thailand, the US, Indonesia and the UK. MPOB plays a significant role in applying and promoting oil palm biotechnology. It has the whole complement of genes, promoters and transformation techniques for producing high oleic oil palm via genetic engineering. Research is on-going on oil palm specifically, and more patents are estimated to be filed as and when the research yields its desired objective.

612 This was confirmed by Patent Division, MyIPO during the interview session carried out in July 2009.

Other RIs and agencies like MARDI, MRB, MCB and FRIM do not however own any patents on techniques in plant breeding technology, although they are also actively involved in research of agricultural biotechnology. MCB is thoroughly researching on transgenic cocoa plants and it expects to succeed in its research efforts some time in the near future.[613]Some of the main area of research in cocoa biotechnology include research in tissue culture and plant regeneration for the mass propagation of superior trees and as a platform for genetic engineering, pest resistant cocoa via in vitro technology and genetic transformation as well as research to produce high flavour Malaysian cocoa and specialty cocoa beans.[614] The latest achievement by MCB is the success in creating partially transgenic cocoa somatic embryos, but transgenic plants have yet to be generated. MCB is anticipating another 10 years to create a fully disease resistant cocoa trees before releasing them to farmers.[615]

5.3.5 Plant Variety Protection: An Alternative

The Protection of New Plant Varieties Regulations 2008 of Malaysia came into operation on October 20 2008, enabling Malaysia's Protection of New Plant Varieties Act 2004 to be implemented.

Since agriculture is one of the major sources of Malaysia’s economy, there is a compelling need to protect the main crops such as palm oil trees, rubber trees and cocoa, not only in Malaysia, but also in other countries which are capable of growing such trees. The introduction of new varieties for these crops is an

[613] As confirmed by the MCB during the interview via email in August 2008.
[614] Refer : <http://www.koko.gov.my/CocoaBioTech/Program.html>[Accessed 08 September 2010]
[615] Refer : <http://www.koo.gov.my/CocoaBiotech?AcDOCTRTPB.html> [Accessed 08 September 2010]

essential component to maintain and sustain good and high crop productivity and quality.

At this juncture, it is to be noted that since the filing of applications to register new plant varieties and grant of breeder's rights in Malaysia only began at the end of year 2008, there is no specific data obtained from the relevant research institutions and agencies, as the interviews for the purpose of data collection were carried out some time from early towards the end of the year 2008. The views of the RIs and the agencies, which could be speculative, on plant variety rights system of protection were gathered and would be analyzed in this Chapter, as they represent a large component of plant breeders in Malaysia. Having said that, the statistics as provided by the Department of Agriculture (DOA) on the current status and numbers of plant varieties application serve as major source on the figures and data relevant for this Chapter. Currently, the cumulative number of applications received by the DOA is 43, and there has yet to be any grant of plant breeder's right, as all applications must undergo processes of examination as spelt out under the 2004 Act as well as the 2008 Regulation.

The following data is the summary of the applications with regard to MARDI, MPOB, MRB, MCB and FRIM.

Table 5.4

Number of plant varieties application by major RIs in Malaysia

Research Institutes / Organization (RIs)	Total number of new varieties application submitted to DOA (as at August 2010)	Details of application (types of plant varieties)
MARDI	14	2 ornamentals 1 vegetable and 11 cereals (rice)
MPOB	0	-
MRB	0	-
MCB	3	Cocoa
FRIM	0	-

Source: Department of Agriculture (DOA)

It is not surprising to note that out of the total of 54 applications received by DOA, 14 applications come from MARDI, 3 applications from MCB, and there are no applications from MPOB, MRB and FRIM.[616] This could be linked to the stand and views taken by MARDI and other remaining RIs on the effectiveness and necessity of the protection via plant breeder's rights. Their views are scrutinized in the following discussion.

5.3.5.1 Issues on patenting of new plant variety

The Malaysian Patents Act 1983 expressly states that plant varieties are not patentable.[617] Hence, it seems that there was lack of formal protection for the new plant varieties in Malaysia prior to the implementation of the 2004 Act, despite the fact that the informal registration of new fruits varieties has been available for certification purposes since the early 1930's.[618] MARDI which had

[616] Other Malaysian applicants include Sabah Forestry Development Authority, Felda Agricultural Sdn Bhd, Universiti Kebangsaan Malaysia, private companies (Malaysian Agrifood Corporation Berhad, Ligno Biotech Sdn Bhd) and foreign applicants from the US and Netherlands. Source : DOA at <http://pvpbkkt.doa.gov.my/> [Accessed 24 August 2010]
[617] Section 13(2)(b) of Patents Act 1983.
[618] Refer : <http://pvpbkkt.doa.gov.my/>

been involved in research of all types of crops which include fruits and vegetables (except oil palm, rubber and cocoa) was looking forward to the implementation of the 2004 Act. Thus, it is not surprising that MARDI has started to submit its applications for plant breeder's rights after the Regulation 2008 came into force. In fact, MARDI has been in the forefront in terms of application for plant breeder's rights as compared to other research institutes like MPOB, MRB, MCB and FRIM.

MARDI takes a firm stand on the ban on patenting plant varieties, holding that the ban should be retained, and all the new plant varieties should be legally protected under the 2004 Act. MARDI is of the view that the 2004 Act provides an effective system of protection for the development of the breeding of the new varieties of plant. The scope of protection offered under the Protection of New Plant Varieties Act 2004 is comprehensive, extending to acts carried out on a commercial basis including producing or reproducing, conditioning for the purpose of propagation, offering for sale, marketing, exporting, importing and stocking the material for the earlier activities. Hence, unauthorized conduct of such acts will constitute an infringement under the 2004 Act.

In addition, MARDI is in full support of the 2004 Act as the limitation that serves as the exclusion to the infringing acts under the Act does facilitate the development of new plant varieties and related research. The 2004 Act specifically states that the rights do not extend to any act done privately on a non-commercial basis or for an experimental purpose or any act done for the purpose of breeding other plant varieties, propagation by small farmers using harvested material of the registered plant variety planted on their own holding, exchange of reasonable amount of propagating materials among small farmers and the sale of farm-saved seeds in situations where non-usage is beyond the control of the farmer.[619] In this regard, MARDI comes under the exception of 'experimental purpose' hence its research activities should not be affected.

MARDI's view on retaining the ban on patenting of new plant varieties could be attributed to the fact that it was primarily established to conduct research to benefit the local farmers' community, by way of providing better variety of crops to upgrade farming activities and yield enhancements. In line with this objective, MARDI does not look at patents as the most suitable tool to help the local farming community in Malaysia, as patenting research output such as seeds would increase the price of a patented seed supply. Any increase in the price may not be in favour of the farmers' interest, and that would not help the local farmers, in particular subsistence and small-scale farmers, as the benefits of a patented seed supply could be insufficient to compensate for its higher price.

One practical example to show MARDI's practice and approach in managing its R&D output is the commercialization of a new variety of sweet potato named 'Vitato'[620] in 1994. This new variety is more nutritious than other types of existing sweet potato variety because of its high B-carotene content as well as the ability to produce a much higher yield. Since the new PNPVP Act 2004 was not available when the variety was released for commercialization, obviously it was neither protected under PVP nor under the Patents Act 1983 which

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619 Section 31(1) Protection of New Plant Varieties Act 2004.

620 Refer MARDI Agricultural Technology Website (MAGRITECH) : <http://agromedia.mardi.gov.my/magritech/tech_detail_fdcrop.php?id=328> [Accessed 08 September 2010]

expressly exclude plant varieties from patentability. The interesting part of this invention by MARDI was that it was publicly available for local farmers for growing purposes via arrangement with MARDI.[621] At this juncture, it is crystal clear that MARDI Agricultural Technology research team is giving priority to improve the living of local farming community via free access to the new variety rather than going into protecting its invention by way of patents or any other means available. The same approach is taken by MARDI in managing and distributing its new rice variety[622] to local farmers throughout the country without any licensing fees whatsoever, with the primary objective of improving the paddy/rice breeding and increasing the productivity level of local rice.

MPOB and MRB on the other hand hold an opposite view of MARDI. Both of these research institutes are proponents of patent protection for their research invention. MPOB and MRB are of the view that the ban on patenting of new plant variety should be lifted in order to give new varieties of plant a strong IP protection via patent system. In addition, they argue that protection via patent regime would generate more income and profit to the country and better economic gain as a whole. Their stand is parallel with the fact that as compared to MARDI which aims to serve and protect the interests of the farmers' community, MPOB and MRB work directly with and for the industry players in their specialized agricultural sector, hence there is a pressing, real need for both of the institutions to secure the strongest protection available for their research efforts and outcome. Having said that, patent protection is perceived as generally providing stronger and better protection ac compared

[621] The same approach was taken by MARDI when another new variety of sweet potato which is virus-free was released in 2005, as the 2004 Act was yet to be implemented at that time.
[622] Over the past 35 years, MARDI has released 34 high-yielding rice varieties. Source : <http://www.mardi.my>

to plant breeder's rights, though this perception continues to be a contentious issue worldwide.

MCB shares the same view with MPOB and MRB, holding that the ban on patenting of new plant varieties should not be retained, for the reason that their forth-coming new high value cocoa varieties deserve strong protection through the patent right for the country's benefit in the long run. This is because as far as commercialization of research and development of any invention is concerned, patents could be used to recoup the investment as well as generating income via licensing. FRIM on the other hand holds opposite view, stating that the ban on patenting should remain on ethical reasons, *inter alia*, patent should never be allowed on life forms which include plant varieties.

To sum up, there are basically two opposite views on the ban on patenting of plant varieties, some of the research institutes are in favour of lifting the ban, while some are of the view that the ban should be retained. As far as the Malaysian Patents Act 1983 is concerned, the issue and discussion remains hypothetical at this moment of time, as the existing law states firmly that plant and animal varieties are non-patentable inventions.[623] In this regard, it is worth noting that neither the Patents Act 1983 nor the Protection of New Plant Varieties Act 2004 makes it clear whether an invention in the form of a genetically modified plant that has, for example, increased resistance to certain types of pests, is patentable if the genetic modification (involving significant human intervention) used to achieve the result can be applied to plants in general and is not confined to any particular variety. It would seem that such inventions may be patentable, provided they fulfill other

[623] Section 13(1)(b) Patents Act 1983.

requirements of the Patents Act 1983, such as novelty, inventiveness, industrial applicability and requirements relating to non-contravention of public order and morality.[624]

As far as the Protection of New Plant Varieties Act 2004 is concerned, although the filing of applications to register new plant varieties and grant of breeder's rights in Malaysia have begun since the Regulation came into operation in 2008, it is too early at this stage to ascertain the problems, if any, that may arise in the implementation of the Act. Undoubtedly, the implementation of the Act could be seen as another milestone for Malaysia's agricultural sector and the country's National Biotechnology Policy as well as its IP protection system as a whole.

5.4 Patent Law versus Plant Breeder's Rights

Further to the preceding discussion on the unclear position of patentability of a plant-related invention which may include genetically modified plants in Malaysia, the relationship and interface between patent law and plant breeders' rights is essentially inevitable in light of modern developments in biotechnology.

From the responses that have been gathered during the interviews, some of the RIs and agencies are apprehensive about patenting varieties of plants though they acknowledge that genes and gene transfer technology at a biotechnological level should be covered by a patent system. In general, plant varieties have hitherto been excluded from the grant of a patent by most patent systems, which include Malaysia, for reasons that seem to be

[624] Section 11 and Section 31 Patents Act 1983.

unclear.[625] Given a choice between the two types protection for their agricultural biotechnological inventions, MARDI, being the proponent of plant breeders right, would obviously opt for the plant variety right system of protection on the reason that such a system is seen to offer the most suitable type of protection for all new plant varieties researched and developed by MARDI. Besides, it is not thought to be in the public interest at large and Malaysian farmer's community in particular to permit such an extensive monopoly over plant varieties, given their communal importance. This view is also adopted by FRIM, taking into consideration the scope of protection covered under the Protection of New Plant Varieties Act 2004.[626]

Surprisingly, MRB shares the same view with MARDI, holding that plant breeder's right would be preferable on the basis of simpler procedure and lower fees, as compared to higher cost incurred in a patent application. MPOB being the proponent of patent protection maintains that patent is still preferable even if the plant invention is equally qualified to be protected under the plant breeder's right system of protection.[627] MCB concurs with this view, justifying its stand on the enormous amount of time and money spent into researching and developing its new high value cocoa varieties. Having invested a considerable amount of money and time in developing innovative products, a patent on the research output would enable commercialization of the invention to obtain returns on investments as well as to generate profits.

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[625] INNES, N.L., *Plant Breeding and Intellectual Property Rights*. Available at: < http://www.agric-econ.uni-kiel.de/Abteilungen/II/forschung/file5.pdf> [Accessed 27 January 2010]

[626] At the time of the interview (June 2008), the Act was yet to be implemented as the 2008 Regulation was only released in October 2008. Hence the view is to some extent based on estimation and expectation.

[627] It is to be noted that MPOB's legal advisor (with whom the interview was made) admitted her lack of knowledge on the plant breeder's right system and its scope of protection, on the reason that it was yet to be implemented in Malaysia. This is to some extent justifiable, as at the time of the interview (June 2008), the Act was yet to be implemented, because the 2008 Regulation was only released in October 2008.

Interestingly, despite the mixed reaction towards the patent system and plant breeder's right, there is a unanimous recognition from all the research institutions and agencies that patents provide much stronger protection than plant breeder's right for the products of biotechnological research.

The gathered responses from the research institutions and agencies on their preferred system of protection for their invention is to some extent translated in the current number of application of new plant varieties, as received by the Department of Agriculture.[628] MARDI has filed a total of three applications, whereas MPOB, MRB MCB and FRIM have yet to file any applications.[629]

To recap, the exclusion from patentability under Malaysian Patents Act 1983 is sufficiently clear to cover plant varieties, yet an invention involving plants seem to be patentable. What remains unclear is whether genetically modified plants can be both patentable as well as registrable under the Protection of New Plant Varieties Act 2004.[630] In this regard, it would appear that Malaysia's position would be consistent to that of international practice. A genetically modified variety would not be patentable but a plant invention that consists of genetically modified cell-lines would be. A clear legal position on this area is vital for plant breeders in Malaysia, to assist them in selecting the best and most suitable IPR in protecting their agricultural biotechnological inventions.

5.5 Commercialization of agricultural biotechnological inventions in Malaysia: Issues and Challenges

[628] As at January 2010.
[629] Refer : <http://pvpbkkt.doa.gov.my/>
[630] AZMI, *supra* Note 423.

As far as research in agricultural biotechnology is concerned, as mentioned in the early part of this Chapter, most of the research activities in Malaysia are conducted by government funded RIs and agencies[631]. Despite having a vibrant research community, Malaysia has lagged behind the international community in terms of translating research into new patents and companies. Among the factors contributing to the poor commercialization rate was the lack of co-located inventors and effective entrepreneurial strategies. This could be attributed to the fact that traditionally commercialization was not the main focus or high priority of these government-funded institutions. In fact, there was to some extent a communication gap between scientists, researchers and academicians on one hand and the commercial sector involving entrepreneurs and business people from the relevant industry on the other.

Realizing the issues and challenges in commercialization of biotechnological products, the Government has taken some pro-active strategies, inter alia, the establishment of the National Biotechnology Directorate (NBD) in 1995 under the Ministry of Science, Technology and the Environment. One of the NBD's goals is on commercializing government-funded biotech research, other than strengthening research capability and capacity in biotechnology, as well as facilitating the development of biotechnology-based industry.

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[631] Research and development in plant biotechnology is also being actively pursued by the large plantation companies such as Guthrie Chemara Research, Golden Hope Plantation Berhad, United Plantation, Eastern Plantation Agency and Sime Darby. These companies have their own research arms and their function is often to serve the requirements and needs of their in-house market. The activities of the private sector are mainly restricted to those areas that have an almost immediate pay-off, hence their research are only focused on oil palm, bananas and ornamentals. Source : FAO report, available at: < http://www.fao.org/docrep/v4845e/V4845E0b.htm> [Accessed 27 January 2010]

Other strategies which have been implemented by the Malaysian government are by ways of grants aimed at translating research to commercialization. The Intensification of Research in Priority Areas (IRPA) is one of the biggest research funds, and the NBD also manages a research fund dedicated to biotechnology. For example, under the Eighth Malaysia Plan, IRPA has an allocation of RM1 billion, RM310 million of which is earmarked for the commercialization of biotech and other projects through the Industrial Grant Scheme (IGS) and Commercialization of Research and Development Fund (CRDF).[632]

Coming back to the research institutions and agencies, based on the information obtained during the interview, all the five RIs and agencies have been commercializing their research products via licensing. Therefore, licensing of patent rights is the most popular and common commercialization pathway among the main research institutions in Malaysia. After all, patent licensing is the most prudent method of generating income from an invention, that is via royalties. MPOB and MCB are in the forefront in terms of patent licensing, as they even license their patents abroad. MARDI, MRB and FRIM have yet to license their patent rights abroad.

Another method of commercialization of MARDI research product is via assignment, that is by way of sale and transfer of ownership of the patent by the assignor to the assignee. In fact, assignment is sometimes preferable by MARDI researchers in commercializing their research products for the reason that such a permanent transfer of their patents to the assignee, would release

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[632] Tang, C.M., *et al.* 2003. *Realizing potential: the state of Asian bioentrepreneurship*. [online], Avalaible at: <http://www.nature.com/bioent/2003/030401/full/bioent731.html> [Accessed 29 January 2010].

them from the responsibility of monitoring the patented inventions in the event there is any patent infringement.

As for MPOB, other than patent licensing, it also generates income from their research inventions via lump sum sale payment or direct sale. The reason is to avoid the risk of uncertain royalties with a licence, hence MPOB in certain research inventions prefers to receive a once only lump sum payment, at the outset, receiving all the value of the patent on one single occasion only. MCB is taking the same approach with MPOB in generating income from their patented inventions. With regard to MRB, in order to boost commercialization for its R&D products, MRB has gone to the extent of setting up certain sub-companies to handle marketing strategies and matters related to commercialization of its inventions. This is for the reason that its researchers are lacking in marketing skills and strategies, hence experts in those areas would do a better job in promoting and commercializing MRB's inventions.

It is interesting to note at this juncture that all the five RIs and bodies are unanimous in viewing that the patent regime is the the best method and most effective protection for their agricultural biotechnological inventions, as compared to other alternative methods like trade secret or contractual agreements. MPOB being the proponent of patent holds that patent is always given priority to protect their R&D products. MRB and MCB concur on this view, with some other additional reasoning, such as patent would enable the investors to recoup their investment and make profits. Ultimately, patent would benefit the country to generate more income in the long run. On the other hand, most of the research institutions and agencies are of the view that trade secret protection is too complicated, risky and unreliable to protect their research products, whereas contractual agreements are not favourable for the reason that such agreements are limited and only enforceable between the contracting parties.

It is worth noting that the commercialization which has taken place in these institutions, present challenges, *inter alia*, as highlighted by MARDI during the interview. It was revealed that as far as MARDI is concerned, the move to commercialization has not resulted in any significant licensing revenue for MARDI, although it has licensed certain patents to some local companies. One reason cited is that the products which are produced by local companies under MARDI patent licensing are having a difficult time to penetrate the market and to compete with existing products. The problem could be attributed to the fact that local companies generally lack capabilities and competitiveness in marketing due to limited funds to be allocated for aggressive marketing strategies.

Essentially, public sector research and development activities have contributed to technical improvements. Nevertheless, progress on the commercialization of such output was limited. This was largely due to problems related to the lack of industry-relevant research and development projects and finance to fund the various stages of commercialization from the laboratory to the market place. A survey[633] of 5,232 projects implemented by the public research institutions and universities during the Sixth and Seventh Malaysian Plans (year 1990-2000) revealed that 14.1 per cent of these projects were identified as potential candidates for commercialization while only 5.1 per cent were

[633] The survey is based on an online article by Aziz, Dato'Mohd Rosli Abdul. *Funds for Agro Bio Industry.* Available at: <http://banktani.tripod.com/bio.htm> [Accessed 01 February 2010]

commercialized. However, an assessment of research and development undertaken in the primary commodity sub-sector indicated that the percentage of commercialization of research and development in industrial agricultural commodities was 8.9 per cent. In this regard, the palm oil sector contributed the highest commercialization rate of 12.1 per cent.

In short, one of the major causes underlying this unfortunate state of affairs is the lack of a strong entrepreneurial environment and mechanisms for commercialization. In this regard, the Government's continuous support and commitment for strong R&D programs at various RIs and universities in agricultural biotechnology should exploit the potential from biotechnology towards accelerating the development of agricultural biotechnology industry in Malaysia. In addition, RIs are obliged to place more emphasis on research related to product and process development for industry in order to generate more research and development projects that can be commercialized.

5.6 Conclusion & Contribution

The future looks promising for agricultural biotechnology in Malaysia, especially with strong endorsement by the Government which recognizes it as a high-end technology to be fully exploited in the twenty-first century, supported with full commitment from various RIs, public universities as well as a number of private companies. Being a country with strong agrarian roots and with the push into agricultural biotech, it is natural for Malaysia to leverage its traditional strengths in the agricultural sector. This Chapter has analyzed the viewpoint of plant breeders in Malaysia on patent protection for agricultural biotechnology R&D outputs as well as their views on plant breeders' right system which has just been implemented.

It is found that patenting activities of R&D inventions in the major RIs and agencies have already taken place for quite some time, but they started to gain popularity and become a trend from the year 2000s onwards. The findings could be seen as positive indicator of the awareness on the importance of protecting their inventions via IPRs notably patents. Besides, patents are useful indicators for identifying the fields where technological advances are being made, and this includes agricultural biotechnology.

The patent regime seems to be preferred by the majority of the RIs and agencies for the reason that it offers strong and reliable protection over inventions, as well as the opportunity to recoup the investment and make profits. Nevertheless, as far as the legal framework is concerned, there is a need to further clarify the scope of patentable and non-patentable inventions under Patents Act 1983, to the effect that an invention in the form of a genetically modified plant would be patentable provided the invention is not confined to any particular variety.

The effectiveness of protection offered under the Protection of New Plant Varieties Act 2004 is yet to be seen, but this pan-Malaysian, *sui generis* form of protection is specifically tailored for breeders of new plant varieties in Malaysia. The protection offered under the 2004 Act, in comparison to the patent system, may be preferable among plant breeders for some reasons, *inter alia*, the lesser cost incurred in registering for a plant variety right. Nevertheless, the time factor to fulfill the requirements of uniformity and stability of a plant variety is a concern which is relevant to be taken into account in ascertaining the best method of protection for such a variety or transgenic plant.

With regard to commercialization of R&D inventions, public sector RIs have produced significant amounts of research on resource-based industries. However, the initiative to commercialize such findings remains limited due to the high costs and risks involved. The Government's role and initiatives are inevitable to provide assistance and support to Malaysian-owned companies to enable them to step forward to spearhead and stimulate the commercialization of findings of local R&D.

All in all, the Malaysian biotechnology industry is on track to accelerate commercialization in biotechnology by the year 2011 with the full support of the National Biotechnology Policy and BiotechCorp.

Chapter 6

Towards A Better Intellectual Property Legal System in Malaysia: A Proposed IPR Model

6.1 Introduction

Innovation and creativity are one of fundamental drivers of progress in most societies. All countries, which include developed and developing countries, have the potential to develop their intellectual property assets, and to reap benefits from them for their people. The ability to manage and exploit innovation and resultant intellectual property rights is a key to success in today's world in which intellectual, rather than physical, assets are one of the primary sources of wealth and competitive advantage. Recognition and protection of intellectual property assets are therefore necessary preconditions for development today. The World Economic Forum Global Competitiveness Report, for example, indicates that a correlation between the protection of intellectual property rights and national competitiveness exists. The 20 countries which were perceived as having the most stringent intellectual property protection were classed among the top 27 in the WEF's growth competitiveness index. Conversely, the 20 countries perceived as having the weakest intellectual property regimes were ranked among the bottom 36 for growth and competitiveness.[634]

Interestingly, many developing countries apparently recognize the importance of a strong IP regime and are increasingly using the protection of IP to grow and expand local innovation-based industries. This Chapter seeks to answer the main research question of this thesis, namely to propose the best way to

[634] World Economic Forum, Global Competitiveness Report 2004-5, available at : < http://www.weforum.org/pdf/Gcr/GCR_05_06_Executive_Summary.pdf> [Accessed 30 September 2010]

protect agricultural biotechnological inventions in Malaysia. The discussion includes an overview of the current IPR legislation in Malaysia, as well as the recent developments for the protection of the agricultural biotechnological inventions in Malaysia. The proposed model which is presented in this Chapter would take into consideration relevant factors, in particular the pace of development of Malaysia as a developing country. The model is also drafted by taking into account all the things learnt and benefited from the existing IPR jurisdictions in Europe and the U.S. as covered in previous Chapters of this thesis.

6.2 Background

6.2.1 Current IPR legislation in Malaysia

Malaysia has a strong IPR regime and ranks high among East Asian countries in IPR protection. Hence, it is not surprising that Malaysia is committed to providing a strong IP protection regime under its National Biotechnology Policy. There are two main streams of protection for agricultural biotechnological inventions namely under the patent regime (Patents Act 1983) and under PVP (Protection of New Plant Varieties Act 2004).

6.2.2 Agricultural Biotechnology Research in Malaysia: Persisting Challenges

Some of the impediments and challenges[635] which are oft-cited; the lack of skilled, experienced manpower in the field of biotechnology, a lack of linkages between industry and R&D, the issue of commercialization and the low

[635] The impediments have been discussed in detail in Chapter 4 (under item 4.3).

percentage of global players are also part of the challenges that contribute to the slow growth of biotechnology R&D.

6.2.3 Why is there a need for an enhanced IPR regime in Malaysia

While intellectual property protection is a necessary pre-condition of development in today's world, such protection has to be supported by other appropriate policies and a deep commitment by governments to establish an effective infrastructure to process and make use of intellectual property rights. Without positive action by individual governments, the intellectual property system will not fulfill its potential as a tool for development, growth and progress.

Government is fully aware of the persisting challenges as mentioned in the preceding discussion, hence it is acknowledged that the country needs to improve and enhance its IPR regime in order to speed up and optimize the growth of its biotechnology industry. This is strengthened by the fact that Malaysia aspires to become one of Asia's top biotechnology destinations, with lucrative biotechnology industry. Hence, it is inevitable that the country needs to strengthen its legislation vis-à-vis IPR protection in order to assure a conducive environment for the development of the biotechnology industry. Being a developing country with such a high aspiration, the question is whether Malaysia needs to adopt the IPR regimes as practised in developed nations, or whether it is viable for the country to formulate and focus solely on a unique *sui generis* IPR model to cater for the needs and protection of those involved in the agricultural biotechnology industry.

In terms of patents statistics, the number of patents applied for in the agricultural biotechnology sector is relatively low if compared to healthcare and industrial biotechnology. For example, from the year 2004-2008, agricultural biotechnology recorded 14.3% patents applied for and 11.9% patents granted, while the substantial percentage of patents applied for and granted comes from healthcare and industrial biotechnology.[636] It is noteworthy that the statistics could serve as indicator of companies' concern about the exclusion of patentability of plants and animal varieties. In addition, some companies may prefer to keep their inventions as trade secrets rather than going through the lengthy, time-consuming process of patenting. However, the number of patents applied for and granted is not the only indicator, yet to some extent they are an important tool to measure the successful commercialization of ideas and IP. Hence, there is obviously a need to enhance the existing IP legislation, in particular in relation to patent laws and PVP laws, in order to stimulate more patent applications with the aim of stimulating more R&D and boost commercialization of the R&D outputs in agricultural biotechnology.

6.3 Some recent developments

Malaysia's ranking in terms of IP rights enforcement has improved to number 27 in 2009, compared to number 33 in 2008. Awareness in terms of patent protection and recognition of its value and importance has risen in Malaysia and the number of patents in force per 100,000 of the population improved in 2009.[637] Thrust seven of the National Biotechnology Policy[638] highlighted the

[636] BIOTECH CORP., 2009. *Malaysian Biotechnology Country Report 2009/2010*, Available at : < http://www.biotechcorp.com.my/Documents/AboutBiotechCorp/country%20report%20double.pdf > [Accessed 04 October 2010].
[637] *Ibid.*

need to improve the country's innovation system by reviewing the legal and regulatory framework. In the context of IP protection for agricultural biotechnological inventions, there have been recent developments. These developments are part of the continuous enhancement of Malaysia's legislative and regulatory framework to create an environment that is conducive to innovation and investment in biotechnology in Malaysia.

Part of this effort involves making regulatory changes to give researchers a share in the ownership of the IP and in the monetary rewards derived from their work. As far as the IPR laws are concerned, the government is undertaking several studies and is reviewing its institutional, legal and regulatory and financial framework.

6.3.1 Draft manual of examination guidelines for biotechnology patents

The government is aware that an efficient and effective IP protection system is necessary to ensure that attainment of protection and rights are rapid and straightforward. In order to achieve this, the administration of the Intellectual Property Corporation of Malaysia (MyIPO) must be improved and strengthen to meet the yearly increase in registration applications and also to ensure that the needs of applicants are met. Other than simple application procedures and speedy registration, availability of quality public search facilities and efficient information dissemination systems[639], clear registration and examination guidelines are essential elements which contribute to a high standard of IP

[638] The National Biotechnology Policy (NBP) was launched in 2005 to provide a development framework for the biotechnology industry in Malaysia.
[639] *Supra*, note 518. MyIPO's online filing system is under PANTAS, which is also an online patents and trademark database.

protection. As far as biotechnology is concerned, there is a real need for patent examiners at MyIPO to have a clear examination guideline in dealing with biotechnology patents, hence a manual of such guidelines has been drafted in last few years. The manual is still in draft form and yet to be finalized, pending various meetings and discussions with stakeholders and representatives from biotechnology industry players.[640]

6.3.2 Review of existing IPR statute by a special committee

The Government, via MyIPO, has recently set up a special committee for the purpose of reviewing and proposing any amendment to the current IPR statutes namely Patents Act 1983, Trade Marks Act 1976, Copyright Act 1987, Industrial Designs Act 1996.

According to MyIPO,[641] the Patents Act 1983 will be undergoing some amendment. There are not going to be any major changes or amendment in terms of patentability criteria, although there is some discussion on whether the industrial application requirement needs to be tightened up in relation to biotechnological inventions. One of the areas of amendment would be defining the term 'microorganism' for clarification purposes. Currently, under Section 13(1)(b) of the Patents Act, 'man-made living micro-organisms', 'micro-biological processes' and 'the products of such micro-organism processes' is not excluded from patentability. However, the Act has no clear definition of such terms. With the definition in place, inventors need no longer be apprehensive on the patentability of their biotech inventions and are encouraged to file patents to protect their innovation.

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[640] Latest update as confirmed by MyIPO via email communication on 6th September 2010.
[641] The Director General of MyIPO has indicated that they are targeting for the Patent Act amendments to be tabled to parliament by early 2011; Source : *supra,* note 9.

Other than reviewing the provisions of the statutes, the committee had also been in meetings with the stakeholders to discuss and obtain feedback in relation to issues relating biotech inventions, transgenic plant and animal inventions, stem cells, genes and so forth. The outcome of the review by the special committee is yet to be made available to the public as the discussions are still ongoing.[642]

6.3.3 Accession to UPOV

To-date, Malaysia has yet to become a Member of UPOV. Although the current Malaysian Act, namely Protection of New Plant Varieties Act 2004 can be said to be 90 percent UPOV-compliant and was created with entry into UPOV in mind, some provisions would have to be revised and amended if Malaysia were to ratify UPOV 1991 pursuant to UPOV Council’s recommendation.[643] Apparently there is no easy way to comply with the UPOV Council’s recommendation in some of the major parts, for example to separate the provision on the lower threshold of registrability for traditional varieties from the current 2004 Act, due to the reason that the Act itself was enacted *inter alia* to provide for the protection of the rights of informal breeders which include farmers, local communities and indigenous people.

Joining UPOV would be a big step forward for Malaysia, as the agricultural sector is dependant on two main crops, namely palm oil trees and rubber trees which need to be protected not only in Malaysia, but also in other countries which are capable of growing such trees. The country's rapidly growing

[642] The information is given by one of the committee members in the special committee, solely for the thesis purpose, as the minute and details of the meeting is confidential.
[643] *Supra*, note 540.

agricultural and horticultural sectors would also benefit from UPOV membership, but the Government is currently giving priority to the implementation of the domestic law over the UPOV accession. Hence, the Government is keen to see the response from the breeders as the 2004 Act has just been implemented in October 2008. The agenda of accession to UPOV is not totally abandoned yet it is held in abeyance. After all, it has been proven that breeders only introduce foreign bred varieties in large numbers in a country after it has gained UPOV membership, which provides a seal of approval that the plant varieties laws in a particular country are up to standard.[644]

6.4 The proposed IP model for Malaysia

The Government, via the National Biotechnology Policy, rightfully identifies the effectiveness of the regulatory framework as a key factor for the development of the biotechnology sector in Malaysia. It is important for a country which has a clearly stated objective in relation to developing biotechnology as an engine for national growth to then reflect such policies in its legal and regulatory framework, especially those directly impacting the area of biotechnology.

6.4.1 Lessons from existing models

This thesis has carefully and purposely selected important models from two main jurisdictions, namely the European model and U.S. model for the purpose of comparison and learning from the their experiences in managing their IP laws vis-à-vis protection of agricultural biotechnological inventions.

[644] For example, South Korea had only national applications for plant protection before joining UPOV in 2002, but in its first year of membership it received 350 foreign applications. Refer : OLLIER, PETER. 2008. *Asia reaps benefit of plant variety laws,* available at : <http://www.managingip.com/Article/1941365/Channel/194878/Asia-reaps-benefit-of-plant-variety-laws.html?ArticleId=1941365&p=2> [Accessed 07 October 2010]

Understandably, both models are from developed nations, whereas Malaysia is currently under the status of a developing country. The selection of the models is premised on the fact that Malaysia aspires to become a developed nation in year 2020. In this regard, it is logical and justifiable for the country to steer its legal and regulatory framework based on the IP laws of developed countries, provided it suits local circumstances and the affected industry.

6.4.1.1 First model: Europe & UK

Chapter Two discussed in detailed the two important systems of legal protection for agricultural biotechnological inventions as currently practised in Europe and UK via patent regime and plant breeder's rights. As far as the scenario in Europe is concerned, the European patent regime is governed under two main sources of patent law, namely the EPC and the Biotechnology Directive (EU Directive 98/44). Under the EPC, plant varieties are considered non-patentable subject-matter and protected only under a specialized plant breeders' rights form of protection. The EU Directive 98/44 which was adopted by the European Parliament and the Council of the EU in harmonizing the national laws of EU Member States is seen as a real need to clear any uncertainty relating to the protection of biotechnological inventions.

(i) Lessons learnt from European model

Plant breeder's rights under the UPOV Convention were initially introduced to provide for a much more appropriate, specifically designed sui generis right and protection for European breeders. It was also felt that plant material could not meet the patent law notion of novelty, and plant breeding programs could rarely be shown to be inventive. In addition, it was thought that it would not be in the public interest to allow plant breeders to have an over-extensive monopoly and it would be difficult for plant material to meet the disclosure requirement. Nevertheless, it has been proven nowadays that with the progress and development in plant bioscience, all the perceived challenges are no longer fully justified. The 1961 and 1978 UPOV Acts which contained a prohibition on protection of the grant of patent right over a plant variety was removed from the text of the 1991 Act of UPOV. The evolution of UPOV indicates that the breeders and inventors in agricultural biotechnology industry in Europe currently have the option to select the best method of protection for their R&D output, either via plant breeder's right or via patent law.

On the issue of patentability of agricultural biotechnological inventions, specifically plant varieties and transgenic plants, the current position in Europe is that a plant variety *per se* remains non-patentable under patent laws[645], but an invention is patentable if it concerns plants or animals provided the technical feasibility of the invention is not confined to a particular plant or animal variety.[646] In other words, provided that a patent application that is directed to a plant-related invention satisfies the patentability requirement of novelty, inventiveness, sufficiency of disclosure, and capability for industrial application, such patents over plants are now permitted under the EPC as patents can be granted for inventions that cover more than a single variety. This observation is made on the basis of the amended EPC, the European Directive and recent European case law as discussed in Chapter Two of this thesis.

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645 For example, Section 76A(1) UK Patents Act 1977 (under Schedule A2).
646 Rule 23c(b) EPC.

In one aspect, European law appears to give priority to the PVR system as plant varieties may be protected by national PVRs or by a uniform Community-wide PVR; European patents are excluded for plant varieties and for essentially biological processes for the production of plants. Nevertheless in reality, the European legal framework does not really reduce the area of possible overlap between the two systems, since the patent system remains capable of covering plant-related innovations notwithstanding the exclusivity of protection of plant varieties under the PVR system. In this regard, it is submitted that the European legal framework is far from drawing a clear demarcation line between the two systems of protection. Instead, the overlap area remains rather broad so that, on the issue of availability of protection, European law is, in its practical consequences, not so different from national systems such as the US systems which expressly accept the patentability of plant varieties.

Turning back to the issue on the European model of IP legal framework in protecting to agricultural biotechnological inventions, it is submitted the current legal position in Europe seems to work quite well for the industry. For example, in UK, until the early 1960s, plant breeding in was largely confined to publicly funded research. This situation changed dramatically in the mid-1960s when Plant Breeders' Rights were introduced in the UK through the 1964 Plant Varieties and Seeds Act. This triggered a rapid expansion of plant breeding as a commercial enterprise in its own right, and paved the way for major advances in the performance, quality and diversity of crop production in UK.[647] It is clear that plant breeders have delivered major advances in the yield,

[647] BRITISH SOCIETY OF PLANT BREEDERS, *Plant Breeding: The Business and science of crop improvement*, Available at : <www.bspb.co.uk> [Accessed 12 October 2010].

quality and performance of agricultural and horticultural crops in UK. In the year 2009, 98% of winter wheat varieties and 97% of spring barley varieties sold as certified seed came from UK breeders.[648] Today, much of the basic research into crop science is still conducted by public sector organizations, but the majority of commercial plant breeding takes place within the private sector. The situation is similar to Malaysia, in the sense that most of the R&D activities of agricultural biotechnology is carried out by government funded bodies and institutions, and some commercial plant breeding take place within the private sector, which includes big corporations like Sime Darby.[649]

Nevertheless, the issue of farm-saved seeds[650] has been one of the major concerns in Europe as some local farmers[651] are dependant on their saved-seed for replanting. The issue might not be that relevant to Malaysia's scenario of farming community, as farmers in Malaysia, for example paddy planters are in practice of obtaining fresh seeds for every season, supplied by relevant government authorities. Nevertheless, the relevant part of the issue is the fact that the concept of the farmers' exemption which has been introduced in UK, exempting 'small farmers'[652] from paying royalties for their farm-saved seed. Under the exemption, small farmers are only authorized to re-use their own seed for planting. The similar approach is adopted by Malaysian's government under the Protection of New Plant Varieties Act 2004, which gives recognition and protection of contribution made by farmers, local communities and

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[648] Refer <http://www.fairplay.org.uk > [Accessed 12 October 2010]
[649] Refer <http://www.simedarbyplantation.com/Plantations_Overview-;_Malaysia.aspx> [Accessed 13 October 2010]
[650] For certain crop species – particularly small-grain cereals, growers used to save their own seed for sowing the following year.
[651] For example, in UK, in year 2001, 30% of farmers were dependant on farm-saved cereal seed for replanting their farm, hence a number of them have objected to the principle of paying royalties on farm-saved seed. Refer : <http://5d.5a.5746.static.theplanet.com/article.php?artid=91> [Accessed 12 October 2010]
[652] Those who produce less than 92 tons of cereal, *ibid.;* Refer Section 9 of UK Plant Varieties Act 1997.

indigenous people[653] towards the creation of new plant varieties under specific provision of the 2004 Act.[654]

Plant breeding remains a vital industry to keep Britain and other European countries competitive in world markets. The introduction and implementation of PVR in UK in particular and in Europe at large has to some extent successfully been used as a legal way to facilitate the development of new plant varieties, seeds and the seed market thus assuring seed quality for farmers. The patent regime on the other hand continues to offer a better, stronger protection for plant related inventions as administered under the EPO. This is particularly the case where technologies can be applied to several different varieties of the same crop, or across a range of different species. Patent protection is inevitable in such a situation as developments cannot be protected under the variety-specific system of PVR.

6.4.1.2 Second model: the U.S.

Chapter Three explored the three types of legal protection currently available for plant-related invention in the US, that is via plant patent, the plant variety protection certificate and the utility patent. Legal protection for plant varieties was introduced in the US long before the development of genetically engineered plants. Such a unique, open system of legal protection in the US could be traced back to historical reasons and local circumstances at that particular point of time. When it comes to contemporary patent protection for new plants and other living things, it helps to know the context that two

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[653] In order to give better protection to the rights of indigenous people, the Malaysian Government had been considering a draft Access and Benefit Sharing Law since year 2002, but as at to-date, the efforts have not materialized into any Act. Refer : <http://www.grain.org/briefings/?id=97> [Accessed : 01 December 2010].
[654] For example, Section 31(1) (d), (e) and (f).

important statutory changes provide. One took place in 1930 (the Plant Patent Act),[655] and the other in 1970 (the Plant Variety Protection Act). In both instances, Congress responded to what industry players said was an inability to get utility patent protection for their inventions on an equal footing with other industries. Congress expanded the scope of patentable subject matter on both occasions.

Such a legal system in the US for the protection of agricultural biotechnological inventions is based on the fundamental role of intellectual property in the promotion of agricultural research and innovation. With an average time to market for each new product exceeding 10 years in most cases, due to stringent regulatory approval timelines, the crop protection industry could not contribute to future investment without patent protection. Since the first commercial biotech crops were grown in 1996, plant biotechnology has been rapidly adopted by farmers in the U.S. Increasingly, farmers are now planting biotech seeds because of the clear benefits they bring. Crops commercialized to date have been modified to improve agronomic traits like insect resistance and herbicide tolerance or a combination of the two.

(i) Lessons learnt from the American model

The present system of legislation and legal framework in the U.S. is very much shaped and influenced by the industry players. Congress responded to breeders' requests in 1930 by enacting PPA, and in 1970, a patent-like system for seed-reproduced plants was enacted, namely the PVPA. The enactment of

[655] The PPA 'was the first legislation anywhere in the world to grant patent rights to plant breeders.' *Imazio Nursery, Inc. v. Dania Greenhouses,* 69 F.3d 1560, 1563 (Fed. Cir. 1995), *supra* note 438.

the PVPA was *inter alia* in response to the exertion by crop seed companies which sought for an IP protection for their sexually reproduced plants. Nevertheless, the significant exceptions inherent in the PVPA proved unsatisfactory among commercial seed companies. As a result, utility patent protection remained desirable to the seed companies. The system evolved in the 1980s when IP protection for crop breeding innovations in the U.S. was expanded, and its enforcement has been strengthened. This has encouraged the development, introduction, and rapid adoption of highly successful transgenic varieties of soybeans, cotton, corn, and canola.

Such an open tri-partite system of protection for plant innovation may not be useful to Malaysia for historical reasons, which are very different to the U.S. As far as the Malaysian situation is concerned, laws and statutes are drafted and enacted by Parliament. In the U.S., as mentioned above, it was obvious that breeders and industry players played an important influence in shaping the legal framework and laws relating to plant inventions, and history has swhon that Congress responded via enactment of new law to assure the relevant legal protection. For example, in the U.S., before 1930, plant breeders who created new types of plants had no claim to the marketing rights or sales of their plants, even though it might have taken them a great amount of time and effort to breed a new plant. Hence the PPA was enacted to help plant breeders make up for the costs of developing new types of plants. Since breeding and researching new plants can take a lot of time, money and effort, having exclusive marketing rights helps make it worthwhile for breeders to keep creating new plants.

Such a scenario is uncommon in Malaysia, taking into account the fact that modern agricultural biotechnology is a new field and the awareness of the importance of legal protection for the R&D output and biotechnology invention is still lacking. In most of public research institutions for instance, obtaining IP protection for an invention was not a culture, until the trend changed in the last few years, in response to the Government efforts to raise the awareness of the importance of IP legislation. Conventional breeders and farmers who have been involved in traditional plant breeding in Malaysia did not encounter the similar problems in the U.S. prior to 1930, as the farming and agricultural industry was not a big industry that required specific legal protection via patent or the like. Besides, Malaysia was a under foreign occupation, until it gained independence in 1957, and the Patents Act of Malaysia was only enacted in 1983.

Malaysia instituted a range of IP laws in the 1980s, including the Patents Act of 1983. The Patents Act has been amended several times, both before and after Malaysia joined the WTO and signed TRIPS in 1995. The Patents Act excludes from patentability the same life-science subject matter excluded in TRIPS, including plant and animal varieties and essentially biological processes. Hence the issue of legal protection of agricultural biotechnological inventions emerged only in late 1990s, after the signing of the TRIPS Agreement, in parallel to the increased concern and active R&D in agricultural biotechnology by public funded institutions like MARDI, MPOB, MRB and the like.[656] The Protection of New Plant Varieties Act of 2004 is a much newer piece of legislation, which has only recently been implemented in year 2008.

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[656] The discussion on the role of these RIs was made in Chapter Four and Five of this thesis.

Another issue which would be a major concern is the interest of small farmers and local companies that may be jeopardized if Malaysia were to adopt the three-tier protection for plant innovation as currently in practice in the U.S. The implementation of such an open system of protection (via plant patent, PVP and utility patent) would undoubtedly attract foreign companies in particular multi-national corporations to file and apply for patent grants over their invention in the country. The statistics and analysis in Chapter Three have shown that for some types of protection, foreign companies would dominate as the majority percentage of patent ownership[657] and the allocation of rights lacking balance is always an issue in such a situation. Based on the U.S. experience, there is a very high probability that if Malaysia were to strengthen its current patent laws, for example by lifting the ban on patenting plant varieties so that they would come under patentable subject-matter, multi-national corporations and big international players would be in the front row to file their patent applications, rather than the small farmers of local RIs.

Those against the patent system in the U.S. argue that it does not recognize or reward the contribution of communities of farmers who have developed, over long periods of time, the landraces that form the basis of the pedigrees of modern crop varieties. In a developing country like Malaysia wherein the small and medium size farming community constitutes an important segment of the industry, it is submitted that the alternative, simpler system as available under the new statute (PNPVA) would gradually gain popularity among local

[657] For example, statistics in Chapter Three (Chart 3.5) show that majority of total ownership of granted plant patents is held by foreign residents.

breeders, though the effectiveness of the protection remains to be seen,[658] vis-à-vis its exceptions and relatively generous exemptions.

6.4.2 The model for Malaysia: a two way approach

Based on the two current model laws as discussed above, it is the finding of this thesis that there is unlikely to be a single IP protection framework that will stimulate innovative plant breeding and work best for the development of agricultural biotechnology industry. Both existing systems of protection via patent regime and PVR are important as they play their own, unique role in providing the suitable methods of protection and a wider option for plant breeders and inventors in agricultural biotechnology.

6.4.2.1 Features of model of IP system for Malaysia

Assessing the optimal level of IP protection for Malaysia is not an easy task. The obligation becomes much more difficult in balancing the rights between the interests of the small farmers, indigenous people and local breeders and those private companies, multi-national corporations in agricultural biotechnology industry. A weak IP right might be more appropriate for local seed systems, for example, in allowing free access of patented seeds to local farmers, but inevitably stronger rights are necessary to protect the commercial and export crops which are part of important commodity for Malaysia such palm oil and rubber trees.

(i) The enhancement of existing Patents Act 1983

[658] As at October 2010, the PVP Office has received a total of 54 applications since October 2008, and there is yet any grant of PBR certificate to the applicants.

It is submitted that stronger IP protection would be much more attractive for inventors and investors in plant breeding and those involved in R&D of agricultural biotechnology. The current scope of patent protection under the 1983 Act is generally at a par with the international standard from various jurisdictions of IP laws, but some enhancement would be plausible as a dynamic move towards strengthening the existing framework.

(a) Clearer provisions and interpretation

The first enhancement that would be of paramount importance is to provide for a clear, express provision to allow patentability of transgenic plants. The current position on the issue of patentability of transgenic plants is only by way of implication. The presumption of patentability of transgenic plants is made on the basis that the Patents Act 1983 does not expressly prohibit their patenting, as they do not fall under any provisions of Section 13 of the 1983 Act which spells out the list of non-patentable inventions.[659] An express provision on this matter would eliminate any uncertainty or potential debate on the patentability of transgenic plants which do not amount to or do not fall under plant variety exceptions.

The second enhancement which is equally essential is to provide for a clearer interpretation for the terms that relate to patent requirements, namely 'inventive step' and 'industrial application' vis-à-vis plant related innovations.

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[659] 13.—(1) Notwithstanding the fact that they may be inventions within the meaning of section 12, the following shall not be patentable:
(a) discoveries, scientific theories and mathematical methods;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;
(c) schemes, rules or methods for doing business, performing purely mental acts or playing games;
(d) methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body:
Provided that this paragraph shall not apply to products used in any such methods.

The draft manual of examination of biotechnological patent is a timely effort that is thought would address these issues of uncertainty in determining the requirement of inventive step and industrial application for agricultural biotechnological inventions. MyIPO is currently finalizing the works on revamping and reviewing the IP statutes of Malaysia, and the tasks include reviewing the Patents Act 1983. With regard to the draft manual of examination of biotechnological patent, it is the pipeline, and the draft would be dealt with and eventually would be finalized after the completion of the review of the related IP Acts.

A clearer provision and interpretation of patent law would make the application for patent and the filing process easier for the patent applicants and eventually facilitate a quicker process of patent examination.[660] Such a matter would eventually contribute towards a better, improved patent system in Malaysia.

(b) The utility innovations is to be made available for plant innovations

A unique feature of Malaysian patent law as compared to UK is on the part of utility innovation. Section 17 of Malaysia Patents Act 1983 provides for the definition, application and conversion from an application for a patent into an application for a certificate for a utility innovation and vice versa. Utility innovation means 'any innovation which creates a new product or process, or any improvement of a known product or process, which can be made or used in any kind of industry, and includes an invention.' Utility innovation has lesser

[660] The formulation of an amended, clearer interpretation would entail a deeper discussion as such a task could only be done *inter alia* by referring to various existing manual on patent examination guidelines from various jurisdictions such as the Europe, the U.S., Japan, Australia and so forth.

requirements compared to a patent which needs to involve an inventive step. Hence, the certificate of utility innovation is actually meant for a less innovative invention. As the term 'any kind of industry' is general and wide and would cover agricultural biotechnology industry, it is submitted that the protection afforded via the certificate should be made equally available to transgenic plants and new plant varieties that are not limited to a single variety.

A utility innovation can be applied for as long as it is new and industrially applicable. Even though the utility innovation is subjected to a substantive examination as a patent application, the omission of the 'inventive step' requirement would enable the applicant to enforce his right more quickly than a typical patent application routine. Any plant related invention that fulfils the criteria of novelty and industrial applicability is submitted to qualify for protection under utility innovation. In this regard, it is noteworthy that the R&D agricultural biotechnological research in Malaysia is largely focusing on the application of existing technology. For example, some RIs in Malaysia have been focusing on two input traits (Bt and herbicide tolerance) and this suggests that part of the nature of R&D agricultural research in Malaysia is only making use of the 'old' technology rather than initiating and venturing into totally new technology. The approach is justified on the premise that it is much more economical and practical to produce certain target crops with Bt and herbicide tolerance, for example, MCB is solely focusing on cocoa plant and all kinds of research activities relating to cocoa biotechnology.

The availability of protection under utility innovation for plant innovation would provide a better option for plant breeders, as there are only two criteria to be fulfilled instead of three. This means that transgenic plants, at any stage of research, that do not fulfill, or have problems in satisfying, the requirement of inventive step, may be protected by way of certificate if utility innovation. After all, much plant breeding is sequential, utilizing the best existing varieties to enhance future ones. While the requirement of 'novelty' is always to be met, that of 'inventive step' may be much lower or in case of Malaysian patent laws, absent altogether. This means that the utility innovation examination process would be faster, because of the omission of one patentability requirement, as compared to patent application.

In one aspect, the proposed approach in allowing utility innovation for transgenic plants and new plants varieties which are not limited to single variety, to some extent parallels to the approach in the U.S. system of plant patent, which allows transgenic plant and plant varieties that propagate asexually to be patented without an enablement requirement. In other words, utility innovation in Malaysia does not require the invention to be 'inventive', while application for plant patents in the U.S. exempts the detailed description associated with utility patents. Such an approach is practical and feasible to facilitate protection for plant-related innovation in Malaysia.

(c) The ban on patenting of plant varieties is to be retained

An important enhancement is in relation to the issue of non-patentability of plant varieties. The 1983 Act is parallel to UK Patents Act 1977, hence lifting the ban on patentability of plant varieties would amount to a drastic diversion from the UK patent laws as well as the European patent laws. It is submitted that the liberal approach adopted by American patent law framework is not suitable for Malaysia, as the R&D in the agricultural sector is still in the hands of public research institutes. This is in contrast to the situation in the U.S, in which multi-national corporations and the private sector are the main players in the industry. After all, the American patent law regime is largely based on historical reasons, which are not applicable or relevant to Malaysia. It is therefore submitted that the Malaysian patent regime should adopt the current European approach in retaining the ban on patenting of new plant varieties, but the scope is restricted in the sense that if the plant invention in is not limited to a particular variety, then patent should be allowed.

Allowing patentability for such plant varieties which are not limited to a single variety is important and would provide assurance and security for inventors, plant breeders and researchers in protecting their inventions. As discussed in Chapter Two, it is reiterated and submitted that in comparison to PVP, the patent system provides for a stronger protection for agricultural biotechnological inventions. The submission is premised on the patentability requirements that the invention must be new, involve an inventive step and applicable for industrial application are relatively easier and quicker to be satisfied, as compared to the DUS requirements to be fulfilled under PVP. The uniformity and stability requirements eventually consume a long period of time, and protection via PVP would only be obtained once a plant variety could be shown as uniform and stable.

On the other hand, under the patent system, an inventor of a transgenic plant (which may embrace a plant variety) has the option to apply for patent protection right from the very early stage of research, for instance patent on genes or plant cells or process. This is because patent rules permit the inventor to apply early to the patent office at a time when many details of the invention have still to be clarified. Further work and investment may be necessary before the invention becomes a marketable product. Allowing patentability of plant varieties (that is not limited to single variety) would be feasible and workable in relation to recent developments in plant bioscience and biotechnology. Some of the latest advancement in plant biotechnology have proven that there would not be much problem in satisfying those patentability requirements under patent laws. In this regard, patent applications could now be filed and granted in most jurisdictions for the invention in the form of transgenic plants provided the patentability requirements are met.

(d) The utilization of research exemption under patent laws is to be optimized

There is reasonable overlap between patent and PVP, and some of the revisions to UPOV strengthen the IP protection and bring it closer to patent-like protection. Both regimes contain provisions for the research exemption, nevertheless, there are fundamental differences between the research exemption under the patent and PVR system. The research exemption is an exception from the infringement of a patent for the purposes of conducting research activities. This allows a person to make use of the patented invention without the permission of the patent owner of the use if meant for 'research' as defined by the patent law. Under the Malaysian Patents Act 1983, the research exemption is incorporated in Section 37(1) which states that: 'the rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research.'

Most jurists are of the view that patents are able to restrict research on plant varieties to a greater degree than PVRs. This is due to the very narrow scope of research exemptions under patent laws, for example, in the U.S., such exemptions are confined to philosophical use and idle curiosity. In contrast, in Europe, member States have adopted research exemptions, inspired by Art. 27(b) of the Community Patent Convention (1989 version), and whose scope is generally broader than that of the American provision. Interestingly, in the U.K., other than the experimental research activities and private acts which have no commercial purposes, the exemptions are much more expansive as compared to Malaysian patent law. Section 60(5)(g) of the U.K. Patents Act 1977 grants a farmers' exemption, similar to the field of plant varieties protection.[661] Hence, farmers and plant breeders in the U.K. stand in a better position, as they are entitled for exemption both under the PVP as well as the patent law regime.

As far as research activities are concerned, especially those carried out by public RIs, they would receive a huge set back without free access to the existing, fundamental technology. In order to ensure optimum progress of biotechnology without obstructions, a policy that would balance the rights of the patentee and that of the public has to be made. Narrow research exemptions would hinder the public from the opportunity to freely use the patented subject matter for their research during the patent term, which would result in stifling research. As far as Malaysian patent law is concerned, it is submitted that the term 'scientific research' which is the activity allowed by

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[661] Section 60(5)(g) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if - it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent or agricultural use.

virtue of research exemption under Section 37 of the 1983 Act is sufficiently broad so as to permit the use of the patented invention for research in particular those carried out by public RIs. To date, there is yet to be any litigation or court decision in Malaysia pertaining to the extent of research exemption under the Patents Act 1983, in spite of the probability that there might be litigation due to the increased use of patented inventions for research without permission from the patentee, in particular if the patent is owned by a private company or multi-national corporation.

In short, research exemption provision under patent law in Malaysia is reasonably broad and proportional to facilitate scientific research activities and this would provide a balanced framework to encourage the progress of agricultural biotechnology. Hence, it is of paramount importance that public RIs should make use of the exemption under the Patents Act 1983 to access patented inventions so that they would be able to boost their research activities and development without undue difficulty. Eventually, it is hoped that the IP holding firms would be unable to block off an area of research and ultimately it would help to strengthen the position of local researchers who are working to develop new technologies using tools that have been patented by others.

(ii) Enhancement of PVP

Identifying the appropriate balance between breeders' needs and farmers and consumers of plant varieties is a matter that has perplexed policy makers worldwide as there are no readily identifiable alternatives. As far as PVP is concerned, the related legislation, namely the Protection of New Plant Varieties Act (PNPVA) 2004 and the Protection of New Plant Varieties

Regulations 2008 are relatively new, as the implementation of the former has only commenced on 20th October 2008 after the gazetting of the 2008 Regulations. Having said that, it remains to be seen whether the PVP regime would actually work in terms of giving the best protection for interested and targeted parties from the agricultural biotechnology industry which include farmers, local communities and indigenous people, other than RIs and private companies.

(a)Protection via PVP is to be encouraged as an option for interested plant breeders and inventors

Protection via PVP has become possible in Malaysia with the establishment of the 2004 Act. The Act was very much welcomed by breeders in Malaysia as prior to the 2004 Act, there was no specific Act protecting the exclusive rights of the breeders of new plant varieties. The Malaysian government realized the importance of PVP for the development of the country. Malaysia, is a member of the World Trade Organization (WTO) and a signatory to the TRIPS Agreement, which under Article 27.3 (b), stipulates that member countries shall provide for the protection of plant varieties by a patent or by an effective *sui generis* system or by any combination thereof. As such, Malaysia is able to fulfill its obligation of Article 27.3 (b) for the TRIPS Agreement with the introduction of the PVP legislation.

The PNPVA is significant in the sense that it is aimed at providing for the protection of the rights of breeders of new plant varieties, the recognition and protection of contribution made by farmers, local communities and indigenous people towards the creation of new plant varieties, as well as encouraging investment in and development of the breeding of new plant varieties in both public and private sectors.[662]

By virtue of the 2004 Act, breeders of new plant varieties in Malaysia are now in a better position to have access to new and improved varieties for commercial growing.[663] PVP under UPOV has been shown to stimulate foreign breeders in making available their modern varieties. It can create an incentive for breeders from industrialized countries to export their best and most recent varieties to countries in which an effective PVP system has been implemented. As far as the Malaysian domestic scenario is concerned, RIs which represent a substantial component of the agricultural biotechnology industry players, for example MARDI, have the option of filing applications to Plant Variety Office under the Department of Agriculture for the protection of their R&D output. The effectiveness of the protection via the PVP in Malaysia is yet to be proven as the Plant Variety Office at this stage is still examining the applications received, and there is yet any certificate of plant variety rights which have been successfully issued to the applicant or breeders.[664]

Since the Malaysian Patents 1983 excludes plant varieties from being made patentable, the PNPVA in one aspect is an exclusive piece of legislation that caters for the protection of new plant varieties. Nevertheless, the situation and latest development in Europe could be taken as a useful guide for Malaysia to develop its PVP system. In this regard, it is submitted, as mentioned in preceding discussion, that the PNPVA is the most suitable, exclusive method

[662] The Preamble of the PNPVA 2004.
[663] Temperate flower growers in Malaysia, for example, are facing problem in getting new varieties from Netherlands and other countries which bred these varieties. Refer : <http://pvpbkkt.doa.gov.my/> [Accessed 25 October 2010]
[664] As at October 2010, a total of 54 applications have been received by the Plant Variety Office, Department of Agriculture. Refer<http://pvpbkkt.doa.gov.my/> [Accessed 25 October 2010]

for the protection of new plant varieties. However, if the plant innovations in the form of new plant varieties embrace more than a single variety, it is proposed that protection for such an invention is to be made available under patent regime. In other words, plant varieties, for example transgenic plants, which may embrace plant varieties but are not limited to single variety, or which do not fulfill the DUS criteria[665] under the PNPVA 2004, should be made protectable under the Patents Act 1983.

Protection by way of PVP in Malaysia should be encouraged as it provides for a cheaper method of protection in terms of fees, and the application process is equally simpler, as compared to patent application process.[666] Nevertheless, contrary to some beliefs and contention, it is submitted that in terms of time factor, protection by way of PVP may in some circumstances, consume a longer period of time, depending on the types of plants. This is due to the uniformity and stability requirements that may consume a long period of time, and protection via PVP would only be obtained once a plant variety could be shown as uniform and stable.[667] In such a situation, patent would provide a faster means of protection, as compared to PVP.

Protection via PVP is necessary in Malaysia as the rights of breeders, local farmers and indigenous people would properly and legally be recognized. The

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[665] Section 14(1) of the PNPVA 2004; Section 14(2) of the Act provides that: 'where a plant variety is bred, or discovered and developed by a farmer, local community or indigenous people, the plant variety may be registered as a new plant variety and granted a breeder's right if the plant variety is new, distinct and identifiable.

[666] Patent application filing is normally handled by a specialized patent agent, whereas under the PVP, the breeders themselves can file the application without the need of an agent.

[667] For example, short term crops or plants, the examination process range from twelve to twenty-four months, for an intermediate term plant such as rubber tree, it ranges from twenty-four to sixty months, whereas for a long-term crop like oil palm, it ranges up to hundred and twenty months (approximately 10 years). The information is provided by PVP Official during the interview session, *supra,* note 536.

plant breeders' rights certificate holder may exclude others from selling the protected variety, producing it for sale and making repeated use of the protected variety as a step to commercially produce another variety. Obviously, PVP is specifically designed to protect the propagating material (including seed, cuttings, divisions, tissue culture) and harvested material (cut flowers, fruit, foliage) of a new variety. The pro-active effort on the part of Department of Agriculture in raising the awareness and promoting the newly introduced system of protection for plant variety to the local breeders and public at large is a vital, commendable effort to contribute to the success of the PVP regime in Malaysia.

Although the current Malaysian Act can be said to be 90 percent UPOV-compliant, some provisions would have to be amended if Malaysia were to ratify UPOV 1991. Hence, Malaysia has yet to join UPOV and in fact, the effort and steps towards acceding to UPOV Convention are currently put on hold, as the Government has prioritized the implementation of the Act over the UPOV accession. Nevertheless, the agenda to accede to UPOV would definitely revive when the need for the accession reemerge in the near future.

6.4.3 The IPR model for Malaysia in a nutshell

To recap, it is reiterated that the American IPR model which is based on three-tiered level of protection is unlikely to fit into Malaysian's circumstances due to historical reasons of such a system, as well as the different level of economic development and slower agricultural biotechnological R&D and the industry growth in Malaysia.

The European IPR model in some aspects, in particular the one in practice and is being implemented in the UK, is submitted to be of very useful guidance for Malaysia. The approach in defining the 'controversial' term and scope of patentability of plant varieties could be adopted by Malaysian legislature in enhancing and amending the Patents Act 1983. Essentially, patentability of the new plant varieties should be allowed, if the plant innovation is not limited to a single variety of plant, provided that all the patenting requirements are made.

In view of providing a conducive regulatory framework via a strong patent regime, and to extend the protection of plant innovation via certificate of utility model, the effort of accession to UPOV is obviously not a matter of priority, at least for five to ten years to come. This is premised on the fact that the Government is obliged to protect the interest of domestic plant breeders, small farmers and indigenous people, on top of developing national capability in agro-biotechnology. The PNPVA 2004 which is a *sui generis* and very much pan-Malaysian by nature, though is inconsistent with a few provision of UPOV, has been carefully drafted, hence it is well justified for the Government to see whether such a system will work for the benefit of the domestic R&D researchers and industry players. Interestingly, although the PNPVA 2004 is not fully UPOV-compliant, it has managed to attract quite a number of applications from foreign companies[668]. All in all, the issue of accession to UPOV would definitely revive when the agricultural biotechnology industry in Malaysia is fully developed, say in ten years to come, parallel to the National Biotechnology Policy and the BiotechCorp's vision and mission.[669]

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[668] To-date, applications from abroad come from the U.S., Netherlands and New Zealand. Refer: <http://pvpbkkt.doa.gov.my/> [Accessed 11 November 2010]
[669] Refer : <http://www.biotechcorp.com.my/Documents/AboutBiotechCorp/BiotechCorp%20Annual%20Report%202009.pdf> [Accessed 11 November 2010]

6.5 Conclusion

In conclusion, it is the finding of this thesis that the exclusion from patentability for plant varieties has to be seen in relation to the aim of the UPOV Convention: plant varieties could and should be protected under this regime and this should remain as an option in the hands of breeders or inventors, whereas other plant-related inventions, which may also encompass plant varieties, not protectable under PVP, should be patentable as any other invention under the Patents Act 1983.

It also the finding of this thesis that the patent system provides a better protection for agricultural biotechnology inventions in most circumstances. Hence, as far as the Malaysian scenario is concerned, for economically important crops like palm oil and rubber trees, RIs such MOPB and MRB are making a right choice by choosing patent protection for their R&D output wherever applicable. Under the patent system, an inventor of a transgenic plant (which may embrace a plant variety) has the option to apply for patent protection right from the very early of research stage, for instance patent on genes or plant cells or process. This is because patent rules permit the inventor to apply early to the patent office at a time when many details of the invention have still to be clarified. Further work and investment may be necessary before the invention becomes a marketable product. This aspect of the patent system provides some security for the inventor, an aspect that is missing under PVP hence may appeal to plant breeders. The recent developments in plant bioscience and biotechnology have proven that there would not be much problem in satisfying those patentability requirements under patent laws.

The exemptions under the PVP are aimed to balance the interests of breeders as the inventors of new plant varieties and farmers as the users of the protected varieties. Interestingly, patent system also provides for research exemptions in order to balance the rights and interests of inventors and society. The experimental use exception is one such aspect of patent law which may be further explored as means of facilitating change. As the current scope and boundaries of the exemptions under patent law are uncertain and has been confined to a very narrow sphere of use in some jurisdictions such as the U.S., this is by no mean an international standard. In this regard, there is a need to explore and benefit from the research exemptions under the Patents Act 1983. In this way, RIs, including plant breeders, and the whole industry players would be able to make full use of the exemptions under the 1983 Act to facilitate the access to patented inventions for their research activities. Legislators and the judiciary would do well to heed calls for clarification. However, any reformulation of the experimental use exception for plant biotechnology should always take into account the legitimate interest of the patent owner.

The patent system in Malaysia can further be enhanced by tackling the issues of uncertainty in some of the terms in the Patents Act 1983. Clarification of the terms such as 'inventiveness' and 'industrial application' would assist both patent applicant and patent examiner in patent filing and patent examination respectively that would eventually contribute towards more efficient patent system in Malaysia. The manual for examination of biotechnology patent which is still at the drafting stage is essential and very much anticipated by the industry players in particular to improve the biotechnology patent application and examination system. The expansion of the utility innovations for plant innovations would provide a wider option for inventors, researchers and plant breeders to make the preferred selection of IPR protection that best suits and safeguards their inventions. In the absence of an effective IPR system, research firms would keep a considerable amount of information about plant genomes and the function of genes for example, secret, thus restricting its use in further knowledge creation and technology innovation.

All in all, the challenge for Malaysia as a developing country is to have an IPR system comprehensive and effective enough to cover technologies of modern agricultural biotechnology, yet ensuring a fair competition so that one or a few corporations do not control the vital inputs of agriculture. The above IP model with the proposed features as discussed above is submitted with the objective of stimulating the transfer of technology and scientific co-operation with industrialized countries, on top of boosting the development of agricultural biotechnology industry as well as protecting and safeguarding innovative activities within Malaysia itself.

Chapter 7

Conclusion

7.1 Introduction

This chapter brings together the results and conclusions from previous chapters. It shall discuss the strength and weakness of this research. Besides, some directions for future research and recommendations are also presented in this chapter. In essence, this research has answered all its research questions and has achieved all its initial objectives.

7.2 Journey revisited

It has been a subject of debate and a matter of dispute whether plants and agricultural biotechnological inventions can be the subject of patent protection, in addition to or as an alternative to the protection afforded by plant variety rights. Biotechnological patents have been criticized for granting an excessive scope of protection to proprietors, whereas plant variety rights have been slighted for not providing enough protection. Hence, this research has been built on few main themes, namely; the discussion on IP protection for agricultural biotechnological inventions as currently in practice in Europe and the U.S., as well as the deliberation on the current system as practised in Malaysia.

The work is aimed at the prospect of Malaysia as developing country to enhance its current IP framework and legislation in order to develop its agricultural biotechnology industry. The research focused on whether there is a single system as a model of IP regime to be adopted for Malaysia in order to provide the best IP protection for its agricultural biotechnological inventions. In answering this question, all the relevant factors and consideration were taken into account, such as the status of Malaysia as a developing country, the pace of biotechnological inventions R&D relating to plants which is much slower in comparison to the development in the Europe and in the U.S., the different nature of farming activities, economic strength, main players in the industry and so forth. Explanatory in nature, this research employed a pragmatic, critical and multi-literature approach to optimize the investigation and exploration of the research questions. The research is unique in the sense that, on top of black-letter law approach, it also employs a qualitative approach in the form semi-structured interview which has been successfully carried out, targeting a number of selected bodies and RIs. Such agencies, bodies and RIs which are mainly public funded RIs represent a substantial component of agricultural biotechnology industry in Malaysia hence would be directly affected by whatever laws which are enacted and implemented in Malaysia. This empirical aspect of the research is vital because it would demonstrate the views as to the appropriateness and effectiveness of the systems available to the researchers and plant breeders in agricultural biotechnology.

7.3 Research limitations

The present research has notable strength and limitations. The first strength is the fact that the recommendations and proposal from this research contributes to the pool of literature in the area of IPR related issues in Malaysia. As modern agricultural biotechnology in Malaysia a is relatively new industry as compared the development in the industrialized nations, literature work and legal writing by Malaysian jurists from the IPR perspective is very much limited as compared to the works and legal references available other jurisdictions notably from the Europe and the U.S.

The other strength of this research is from the empirical part of it. The information gathered from the semi-structured interviews with the targeted RIs and bodies are valuable as it was the first hand, reliable data and inputs that came direct from the legal section of those RIs and bodies.

Nevertheless, there are some inevitable limitations in the research. The information and evidence used in this analysis have been partly furnished by way of referring to patent law and policies of European countries, in particular the U.K. as well as the U.S., judicial cases and secondary resources, based on the works of other writers. The researcher did not have the opportunity to organize field work to gather empirical data in those selected countries personally, hence no direct information or interaction with the local experts from those countries. Nevertheless, the researcher is of the opinion that the information gathered from the official websites of relevant bodies are highly credible and reliable. The data has been of paramount importance in formulating the proposal in the form of IP model for Malaysia as incorporated in Chapter 6.

The other limitation is concerning the targeted RIs and bodies as the interviewees for the semi-structured interviews. The selection of the targeted interviewees was made on the basis that they are the substantial component of those involved in R&D for agricultural biotechnology in Malaysia. Therefore, they are, to some extent, representing the important players of the agricultural biotechnology industry in Malaysia. The researcher did not have the opportunity to extend the interview to the legal department or unit private companies that are involved in agricultural biotechnology due to time constraints as well as due to the fact that most of the private companies and corporations were reluctant to be interviewed on the reason of data confidential policy of their respective companies.

7.4 Conclusion

The researcher has given her best effort in this research in order to fulfil its objectives. Broadly, the conclusions of this thesis are;

First, both existing systems of protection in Malaysia via patent regime and PVR are important as they play their own, unique role in providing the suitable methods of protection and a wider option for plant breeders and inventors in agricultural biotechnology.

Second, there is a need to enhance the Patents Act 1983 via some amendments to certain provisions, *inter alia,* to clear any ambiguities inherent with certain terms relating to patentability requirements , as well as to provide for express provisions allowing for patenting of transgenic plants.

Third, the certificate of utility innovation is to be extended and to be made applicable for agricultural biotechnological inventions, which include new plant variety which is not limited to a single variety of plant.

Fourth, to adopt European approach in allowing patentability for new plant varieties which are not limited to a single or a particular variety, if all patentability requirements are met.

Fifth, to optimize the use if research exemptions under the Patents Act 1983 for the benefits of R&D research, in cases where such research activities require access to patented inventions.

Sixth, to encourage the utilization of PVP system to interested plant breeders and inventors, as the system has its own merits and benefits in particular to protect new plant varieties.

There are questions and concerns whether the IP models (namely the European and the American[670]) which are based on the system of industrialized nations would fit into the current context of Malaysia, a developing country. The answer seems to be affirmative as Malaysia aspires to be a developed country by year 2020 and the Government's policy and efforts are all geared towards boosting the growth of the country's agricultural biotechnology industry. Nevertheless, there is certainly no single model which would work best for Malaysia, but the effort to strengthen and tighten up the IP legislation is submitted as one of the best option to provide a conducive environment for patenting activities in the country. At the same time, the interest of small farmers' community, indigenous people and small-medium sized local biotechnology companies must not also be neglected.

7.5 Recommendations

The issues of the effectiveness of PVP system in Malaysia could be investigated further. It would be essential for future research to assess and improve the analysis on the benefit of the system to the plant breeders in Malaysia, based its implementation. At this point of time, the PVP has just been implemented and there is yet any certificate of plant breeder's rights granted to any applicant.[671] The study on the positive impact and benefit of the PVP system would be beneficial to promote the system to the industry players in agricultural biotechnology.

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[670] As far as the US laws are concerned, the FTA negotiations between the US and Malaysia, once concluded, will definitely affect the current legal framework of Malaysia. Both countries launched negotiations on 8 March 2006 in Washington D.C. To date, eight rounds of negotiations have been held. IPRs were one of the issues discussed during the negotiations. Negotiations were put on hold as both countries reviewed their respective positions. Malaysia is now negotiating with the US within the Trans-Pacific Partnership (TPP) arrangement. Refer Malaysian Ministry of Trade and Industry official website : < http://www.miti.gov.my/cms/content.jsp?id=com.tms.cms.section.Section_55af1514-c0a8156f-2af82af8-1bbb377f> [Accessed 30 November 2010].

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APPENDICES

For reference only:
Questions prepared and used during the semi-sctructured interview sessions with various RIs in Malaysia

AN INTERVIEW ON THE LEGAL PROTECTION OF AGRICULTURAL BIOTECHNOLOGICAL INVENTIONS IN MALAYSIA
(A PhD research)

LIST OF QUESTIONS

These questions are aimed to solicit information to assess the appropriateness and effectiveness of the existing legal protection vis-à-vis intellectual property rights (namely patents and plant variety rights protection) available to those involved in agricultural biotechnology and industry players. The interview also seeks to identify those areas where further legislative activity might be needed. The information and data received is solely for my PhD research purpose.

Thank you for completing these questions

QUESTIONS

[1] Details about Your Organization

[1.1] (a)Name of Organization:

(b)Address:

(c)Name and Position of the Respondent/Interviewee:

[1.2] State the nature of your Organization's business. Where your business involves several activities, please list them and indicate the main one(s).

[1.3] Is your organization business confined to Malaysia?
Yes / No

[1.4] If 'no' to 1.4, please list the foreign countries where your organization operates and state its business activity or activities in each such foreign country.

[1.5] Does your organization collaborate with foreign organizations in the area of agricultural biotechnology?
Yes / No

[1.6] If 'yes' to 1.4, please list the foreign organizations and the countries where they are based.

[1.7] How many fulltime employees does your organization currently employ?

[2] Details About Your Agricultural Biotechnology Unit

[2.1] If agricultural biotechnology is only a part of its business, how many years has your organization been involved in this activity?

[2.2] Please list the plant species your organization is working.

[2.3] Does your organization have a department or an employee solely engaged in managing the organization's patent, trademark and other intellectual property rights?
Yes / No

[2.4] If 'no' to 2.3, does your organization rely for that expertise primarily on

(a) Patent Agents?	Yes / No
(b) Legal advisors?	Yes / No
(c) Legal divisions of associated firms?	Yes / No
(d) Plant Variety Rights Office?	Yes / No

[2.5]
(a) What percentage of your organization's employees are engaged on research relating to agricultural biotechnology?

(b) How many of your employees are fulltime research staffs?

[2.6] What percentage of its financial resources does your organization commit to agricultural biotechnology and related R & D?

(i) 1-5%
(ii) 6-10%
(iii) above 10% (please specify)

[2.7]
(a) Is your organization party to a joint R & D venture relating to agricultural biotechnology?
Yes / No

(b) If 'yes' to (a), what were the main reasons for your organization entering the joint venture(s)?

[2.8] Does your organization carry out subcontract research relating to agricultural biotechnology for other organizations?
Yes / No

[3] Intellectual Property Rights: Patents

[3.1] Has your organization ever applied for a patent for any purpose in Malaysia?
Yes / No

[3.2]
(a) In what year was your first Malaysian patent application made?

(b) Was this application successful?
Yes / No

(c) What was the invention concerned with?

[3.3]
(a) What percentage of your organization's patent applications (foreign and Malaysian) are rejected?

(b) How many Malaysian patents does your organization currently hold?

[3.4]
(a) Does your organization hold patents abroad?
Yes / No

(b) If 'yes' to (a), how many foreign patents does it hold?

(c) If 'yes' to (a), in which foreign countries does your organization hold patents?

[3.5] How many patents does your organization apply for each year
(a) in Malaysia, and

(b) abroad?

[3.6] How many patents are granted to your organization each year
(a) in Malaysia, and

(b) abroad?

[4] Patents Relating to Agricultural Biotechnology.

[4.1] How many of your organization's current patents relate directly to, or specifically protect techniques applicable to plant breeding and seed technology

(a) in Malaysia?

(b) abroad (give countries)?

[4.2] Is your organization's current number of patents relating directly to, or specifically protecting techniques applicable to, plant breeding and seed technology more or less than it was

(a) 1 year ago?	More / Less
(b) 5 years ago?	More / Less

(c) 10 years ago? More / Less
(d) 20 years ago? More / Less

[4.3] What typical problems does your organization encounter when it applies for a patent

(a) in Malaysia, and

(b) abroad?

[4.4] At present, a patent cannot be granted under Malaysian patent law for a new plant variety.

(a) Would your organization like to see this ban on patenting deleted from Malaysian patent law?
Yes / No

(b)If 'yes' to (a), why would you like to see the ban deleted?

(c) If 'no' to (a), why would you like to see the ban retained?

[4.5]
(a) If the ban on patenting a plant variety were deleted from Malaysian patent law, would your organization patent its new varieties rather than seek plant variety rights for them?
Yes / No

(b)If yes' to (a), why would your organization choose a patent over plant variety rights?

(c)If 'no' to (a), why would your organization choose plant variety rights over a patent?

[4.6] It is possible in some countries (eg the USA) to patent a new plant variety.

(a) Has your organization applied for a patent on a variety in any such country?
Yes / No

(b) If 'yes' to (a), was the patent application successful?
Yes / No

(c) If 'yes' to (a), what kind of variety was involved in the application?

(d) If 'no' to (b), why was the patent application not successful?

(e) Do you have a patent application pending in any such country in respect of a new plant variety?
Yes / No

[4.7] If Malaysian law were to be amended to allow the patenting of plants, should patent protection be available for

(a) families or species,	Yes / No
(b) varieties,	Yes / No
(c) whole plants	Yes / No
(d) parts of plants?	Yes / No

[4.8] It appears possible both in Malaysia and abroad to patent a gene.

(a) Has your organization ever applied for a patent on a gene

(i) in Malaysia?	Yes / No
(ii) abroad?	Yes / No

(b) If 'yes' to (a), was the patent application granted, or is it still pending?
Granted: Yes / No   Pending: Yes / No

(c) How many applications by your organization to patent specific genes are currently pending?

[4.9]
(a)Does your organization agree that patent protection should be available for genes?
Yes / No

(b) If 'no' to (a), why does your organization believe that this protection should not be available?

(c) If 'yes' to (a), why does your organization believe that this protection should be available?

[4.10] What does your organization think are likely to be the long-term economic effects of allowing genes to be patented

(a) on your plant breeding programmes?

(b) on investments in agricultural biotechnology?

[4.11] Given a choice, which of the following forms of intellectual property would your organization prefer for new plants that your organization breeds or discovers,

(a) patent protection only?	Yes / No
(b) existing plant variety rights only?	Yes / No

(c) A new form of plant variety rights which affords greater protection than the existing form of plant variety rights? Yes / No

(d) both patents and plant variety rights? Yes / No

(e) a choice between plant variety rights and patents? Yes / No

(f) a new form of protection covering plants and agricultural biotechnology, based on the general idea of plant variety rights but affording greater protection than the existing form of plant variety rights, but not patents?
Yes / No

[5] Intellectual Property Rights: Plant Variety Rights (PVR)

[5.1] Has your organization ever applied for plant variety rights (PVR) in Malaysia?
Yes / No

[5.2]
(a)In what year was your first Malaysian application to the Plant Variety Rights Office at Kuala Lumpur (PVRO) made?

(b) Was the application successful?
Yes / No

[5.3]
(a) What percentage of your organization's applications to the PVRO for PVR are successful?

(b) On what ground(s) or for what reason(s) does the PVRO typically reject your organization's applications?

(i) Lack of distinctness Yes / No
(ii) Insufficiently uniform Yes / No
(iii) Insufficiently stable Yes / No
(iv) Other (please specify)

(c) Has your organization ever applied against rejection of an application for PVR?
Yes / No

(d) How many Malaysian PVR certificate does your organization currently hold?

[5.4]
(a) Does your organization hold plant variety rights certificates abroad?
Yes / No

(b) If 'yes' to (a), how many foreign certificates does your organization hold?

(c) If ‘yes’ to (a), in which foreign countries does tour organization hold such certificates?

[5.5] Is your organization’s current number of plant variety rights certificates issued by the PVRO more or less than it was

(a) 1 year ago?	More / Less
(b) 5 years ago?	More / Less
(c) 10 years ago?	More / Less
(d) 20 years ago?	More / Less

[5.6] (a) Having regard to your response to 5.5, is the number restricted by the capacity of the system?
Yes / No

(b) Having regard to your response to part (a) of this question, which crops are most affected?

[5.7] Having regard to your response to 5.6, would you submit more varieties to PVRO if you could do so?
Yes / No

[5.8] How many plant varieties does your organization submit for plant varieties rights each year
(a) in Malaysia, and

(b) abroad?

[5.9] How many plant variety rights certificates are granted to your organization each year
(a) in Malaysia, and

(b) abroad?

[5.10] What typical problems does your organization encounter when it applies for a grant of plant varieties rights
(a) in Malaysia, and

(b) abroad?

[5.11] Does your organization apply for plant variety rights on its new varieties
(a) because there is no alternative intellectual property protection currently available?
Yes / No

(b) where alternative protection is available, because plant variety rights afford the better legal protection for plant varieties?
Yes / No

(c) where alternative protection is available, because the alternative costs more to obtain than does plant variety rights protection?
Yes / No

[5.13] What reforms, if any, would your organization like to see made to the present plant variety rights system in Malaysia?

(a) System of examining applied for varieties:

(b) Extent of the protection given by PVR:

(c) Use of protected varieties in commercial breeding programmes:

(d) Other desirable or necessary reforms

[6]Commercialization

[6.1] How does your organization commercialize its R&D plant-related innovations / patented agricultural biotechnology inventions / protected varieties

(a) in Malaysia:

(i) direct sales?	Yes / No
(ii) licensing?	Yes / No
(iii) wholesale?	Yes / No
(iv) retail	Yes / No
(v) Other method (please specify if any)	

(b) abroad:

(i) direct sales?	Yes / No
(ii) licensing?	Yes / No
(iii) wholesale?	Yes / No
(iv) retail	Yes / No
(v) Other method (please specify if any)	

[7] General Question

[7.1] If your organization is in favour of deleting the current ban on patenting plant varieties in Malaysian patent law, what benefits can you see arising from this?

[7.2] (Alternative to 6.1) If your organization is in favour of retaining the current ban on patenting plant varieties in Malaysian patent law, what benefits can you see as arising from this?

[7.3] Do you think alternative method of protection (for example trade secret, contractual agreement etc) is more effective/better in protecting the agricultural biotechnological inventions?
Yes / No

Please state your reason:

[7.4] Are there any questions not in this questionnaire that you feel should have been included?

 # Thank you #

Please return the completed questionnaire to:
SUZI FADHILAH ISMAIL
Email : **suzi@iiu.edu.my**
(PhD Candidate, University of Nottingham, United Kingdom.
& Lecturer)
Private Law Department
Ahmad Ibrahim Kulliyyah of Laws
International Islamic University Malaysia
Tel (O): 03-61964354
Fax: 03-61964854
(Hp): 012-9741376