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Malaysian Agricultural Biotechnology: An Outlook on Recent Developments, Regulatory Framework and Impediments

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Abstract: 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. Thus, this paper examines the growth and development of Malaysia's biotechnological sector, focusing on the agricultural biotechnology. Itessentially covers the discussion on the Malaysian National Biotechnology Policy (NBP), the legal and regulatory framework affecting the agricultural biotechnology in Malaysia which includes patent law and plant variety rights, as well as the impediments encountered by the industry to the success of biotechnological R&D.

Key words: Biotechnology, agricultural biotechnology, patent, plant variety rights

INTRODUCTION

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 15,000 flowering plants species and 185,000 animal species. These flowering plant species account for 9% of the world's total while the animal species account for 16% of the world's total. 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.The Malaysian Government in its Ninth Malaysian Plan (2006-2010) is making concerted effort to create environment that is conducive to innovation and investment in biotechnology. 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 Tenth Malaysia Plan (2011-2015) is in synchrony with the second phase of the NBP which aims to transform "Science to Business". Among the main target to be achieved in the biotechnology industry is the establishment of twenty global biotechnology companies in Malaysia.

Materials and Discussion:

The National Biotechnology Policy (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 andinfrastructure. 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 provides anintegrated platform for participation bythe scientific, business and funding groups to ensure an eco-system that is capable of sustaining Malaysia's growth and progress in biotechnology.

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 to emerge as a global biotechnology participant, which is planned to kick-start from the year 2016 to 2020 and beyond.

By implementing its comprehensive Biotechnology Policy in 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

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BiotechCorp in 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.

Legal and Regulatory Framework:

The International Treaties:

Malaysia is a member of the World Intellectual Property Organization (WIPO) and a signatory to the Paris Convention and Berne Convention which govern IPRs. In 2006 Malaysia acceded to the Patent Cooperation Treaty. In addition, Malaysia is also a signatory to the TRIPS Agreement signed under the auspices of the World Trade Organization (WTO). Therefore, Malaysia's IP rights regime is in compliance with international best practices and provide for adequate protection to both local and foreign applicants. According to the International Property Rights Index 2012, Malaysia is ranked 39 out of 130 countries in terms of intellectual property protection and has one of the strongest IP regimes in Asia.

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 and geographical indications 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.

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.

The enhancement of legal and regulatory expertise – with a focus on IP - is a key to the continued growth and progress of biotechnology.

IP Protection for Agricultural Biotechnological Inventions in Malaysia: Patent and Plant Variety Protection:

As far as Malaysian IP system is concerned, there are two main regimes which are currently in force; via patent law and plant variety protection (pvp) 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), supplemented by the Protection of New Plant Varieties Regulations 2008. These two methods of protection will be discussed in turn.

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 domicile 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 legislations 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.

Scope of Patentability:

In relation to the threshold of patentability under the Patents Act 1983, it generally follows the standard of other jurisdiction of patent regime, in particular the practice of European Patent Office (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 Intellectual Property Corporation of Malaysia (MyIPO) pertaining to the new knowledge, latest invention and development on biotechnology. One of the ways

to enhance the knowledge, skills and expertise of the patent examiners is via intensive trainings for them in the field of biotechnology specifically.

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 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 stand is consistent with the TRIPS Agreement as enshrined in Article 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. At this juncture, it is to be noted that despite Malaysia's manifest intention to go big into the biotechnology industry, as far as its patent law is concerned, there has not been much effort apparently in terms of amending Patents Act 1983 to reflect the envisaged goal. Nevertheless, MyIPO in the last few years has started the initiatives to review the IP related legislation to keep pace with the latest technological development, and the exercise will include the review of Patents Act 1983.

As far as 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 yet a member of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. As of 30th April 2011, 78 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.

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 like manufacturing and so forth. Hence, the properly documented current data on biotechnology patent is only available on general basis, for example, MyIPO confirmed that there is a total of 385 biotechnology patents application in the year 2008.

The summary of patent biotechnology application and granted application from the year 1986 to 2008 as provided by MyIPO is incorporated in the table below:

Table 1: 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 2: 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 registry of 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 granted to the local applicants. The table also shows that out of a total 385 biotechnology patent applications in 2008, only 64 comes from Malaysia, and these local applicants range from individuals, universities, research institutes and companies. Local universities contribute to the highest number of application; a total of 43 out of 64 biotechnology patent applications. This could be attributed to the fact that Malaysian government in creating an enabling environment for biotechnology has been allocating a substantial monetary funding for public universities, as well as research

institutions, to be utilized in R&D, *inter alia* biotechnology research. After all, R&D in biotechnology in Malaysia is dominating 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. 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. 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. There has yet to be any case in Malaysia that deliberates on the scope of the exclusion of patent rights on plant varieties. 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 overlapping of patents and plant variety rights. This approach is based on the premise that criteria of 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 plant variety right is rejected outright. 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 come up with 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.

Protection of New Plant Varieties Act 2004:

Since the early nineteenth century, in agriculture and forestry, the introduction of new varieties is 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, 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. The approach is in fact in consonance with the Third National Agriculture Policy (1998-2010).

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. 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, as well as to encourage 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 variety. 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 as well as documenting traditional varieties. 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.

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. The drafting of the Act has been done through consultation process with various relevant ministries and other government agencies, research institutions and non-governmental organizations including the Third World Network. 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. 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 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.'

Salient features of the Protection of New Plant Varieties Act 2004:

(i) Threshold of Registrability:

The 2004 Act adopted the UPOV system and mandates the threshold of registrability to be new, distinct, uniform and stable, hence the practice of examination of plant varieties in Malaysia is to be at par with international practice. The kind of exclusive rights granted to the breeder is 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).'

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.

(ii) 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 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.

(iii) 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. 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.

(iv) 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. 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 based on the yardstick and 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 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 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.

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 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.

(v) Traditional Variety:

One of the unique parts of the 2004 Act is pertaining 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. The requirements of uniform and stable are waived in relation to traditional varieties, and they enjoy a much shorter period of protection, that is fifteen years.

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.

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.

(vi) Process of Application:

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 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 years 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 eight 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.

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.

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 come into operation on 20th October 2008. Following this, the Malaysian PVP office has started to accept application for registration as from 1st November 2008. Applications are made using form PVBT 1 together with the guidelines and appropriate technical questionnaire. Foreign application 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 samples, registration of new plant variety and grant of breeder's right as well as compulsory licence.

At present, there are approximately 50 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 SerdangSelangor which was established in the year 2008, is equipped with facilities such as fields and greenhouses for conducting growing tests. In order to enhance the examination skills and expertise of the examiners, a number of trainings have 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.

The summary of the plant varieties application is published on the Malaysian Department of Agriculture's (DOA) website (http://pvpbkkt.doa.gov.my/) and the list is updated regularly. As at October 2012, the total number and status of application are as follows:

The total number of the application which has been received by the PVP Office from December 2008 to October 2012 is relatively small yet encouraging and this could be attributed to the fact that the PVP Regulation has just been released for less than four years. It is expected that more applications would be received by the PVP Office in the year 2013 from various government agencies like MARDI which is actively carrying out the on-going agricultural-based researches. The Office also confirmed that they have been receiving numerous inquiries on the matters related to the registration procedures of the newly system, which is to some extent showing escalating interest on the protection of plant varieties among Malaysian plant breeders.

Table 3: Number of application for plant varieties application submitted to the DOA.

Plant Varieties	Cumulative Number Of Applications December 2008 – October 2012
Fruits	11
Ornamentals	32
Industrial Crops	9
Forest Pants	19
Cereals	18
Vegetables	5
Herbs	2
Mushroom	3
TOTAL APPLICATIONS	99

Source: DOA

Table 4: Status of the plant varieties application.

Status Of Application	Cumulative: December 2008-October 2012
Application Accepted	73
Application Granted PBR	25
Application Withdrawn	1
Application Refused	0
Application Revoked	0
Application Cancelled	0

Source: DOA

In is interesting to note that the PVP Office has been pro-actively promoting 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 the application for the protection under the new system. For example, ornamental flower growers and producers in Cameron Highlands Pahang are not really interested with the application due to lack of awareness of the benefits from the protection of their variety. In addition, they have been relying on the 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.

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. Since Malaysia does not sign the 1991 Act, 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.

Malaysia has the intention of joining the UPOV fraternity with the aims *inter alia,* to enable access to improved foreign varieties such as ornamental 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 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 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),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 the right. Section 14(2) of the Act reads: 'Notwithstanding subsection (1), 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 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, and it always takes years and years, before a new Act could actually be passed and implemented, hence to come up with a separate Act for the protection of farmers is possible yet time-consuming. As a matter of fact, 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. 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. 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.

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 is not 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 reemerge in the near future, or perhaps with the pressure from the UPOV Council or other developed countries.

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, 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. The preceding discussion reveals that Malaysian Government in particular has taken up a number of pro-active steps in order to boost up 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. 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 there are currently only about 400 scientists and researchers for every one million

population by the turn of the century, whereas demand is expected to be 1,000 scientists per one million. 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. Arts graduate (humanities, law, economics and business) accounted for 60 percent of the total graduates produced in the Sixth Malaysia Plan (1991-1995). Medicine, dentistry, agricultural sciences and pure sciences accounted for 25 percent of the total graduates. Graduates majoring in engineering, architecture and town planning and surveying remained at 15 percent. 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 the 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.

(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 intellectual property system in Malaysia. Prior to 2007, an average patent registration process took 5 to 6 years before a patent could be successfully registered. 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, 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 clarity during the patent examination process is somehow 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'. For example, a detailed explanation and interpretation is provided for the important terms pertaining to patentability such as 'inventions', 'industrial application', 'novelty', 'inventive step' and so forth.

(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, especially when dealing with breakthrough technologies arising from basic research, for instance from university's research. In this regard, the proposed strategy and the 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.

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 mechanism 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 mechanism to link key parties necessary in commercializing research findings.

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 has taken the initiative to establish 'the Special Taskforce to Facilitate Business' or PEMUDAH

(taken from the taskforce's Malay name '*PasukanPetugasKhasPemudahcaraPerniagaan'*) on 7th February 2007. 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 has 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 have been 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 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 have 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.

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.

Conclusion:

In short, while Malaysia has identified biotechnology and agriculture as key economic drivers, commercialization of local grown technology is still at 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 this paper, 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 resources to meet the requirement along the value chain of each biotech product, from R&D right through commercialization to prevent unwarranted delay.

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