LEGAL POLICY ISSUES IN THE MALAYSIAN BIOTECHNOLOGY INDUSTRY

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ABSTRACT

The Malaysian biotechnology (biotech) industry is littered with many small companies with different profiles. The country and its local enterprises face significant challenges in their quest to build and develop the local biotech industry. Furthermore, there are several unresolved legal policy issues with respect to the interpretation of the patentability requirements for biotechnological inventions. This paper looks at the concept, definition and standard of *novelty* for biotechnology inventions in light of the developing legal policy on biotech in Malaysia. The understanding of this and other legal, financing and policy challenges faced by local biotechnologists is important. It would assist Malaysia in formulating initiatives that encourage local technological advancement and the protection of domestic economic interests, while remaining competitive and attractive to foreign investment.[1]

Introduction

In order to achieve its Vision 2020[2], Malaysia has identified biotechnology (biotech)[3], as a key driver for economic growth.[4] Malaysia has the right ingredients for developing a competitive domestic and international biotech industry. The country is rich in biodiversity, has a sound financial system, and enjoys a strong governmental commitment to research and development (R&D). The future looks even brighter. Shortly after its accession to the World Trade Organization (WTO) in 1998, the Government amended its *Patent Act (1983)* to conform with the requirements of the TRIPS Agreement.

Article 27 of the TRIPS Agreement only stipulates certain minimum standards for intellectual property protection that all Members must satisfy. Therefore, as a matter of policy, Malaysia could, for example, enact stronger patent laws, such as broadening the scope of patentable subject matter. The resulting financial rewards for innovators and the country would provide incentives for the generation of new interest for R&D activities.

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[1] Once a biotechnological invention satisfies the novelty and the other two patentability requirements, he would be rewarded with patent protection for his incentive in research and innovation. The reward incentive makes research and innovation activities very rewarding. It thus encourages further innovation, while attracting new players to join in the research community.

[2] First announced by Dr. Mahathir, Malaysia's fourth Prime Minister (1990).

[3] Ahmad Badawi, Malaysia's fifth Prime Minister, during the launch of the Malaysian National Biotech Policy (2005).

[4] Dato' Sri Mohd Najib, Malaysia's sixth Prime Minister during the Mid-Term Review of the Ninth Malaysian Plan (2009).

Usually investors are only keen to invest in foreign countries if their economic interests and rights are adequately protected. In light of this, Malaysia could also provide a more enhanced patent system, which provides adequate safeguards for investors.

Further, lowering patentability requirements would also enable the Government to grant utility model[5] protection to inventions which otherwise would not qualify for patent protection. Presumably this would make it easier for new, small or inexperienced local biotech companies to satisfy the novelty requirement for protection. Such an approach would advance the goal of intellectual property law in encouraging R&D activities that facilitate the creation of new technologies. Malaysia faces tough challenges in providing a balanced patent law. A strong patent regime would promote technological progression, and consequently infrastructural development. However, there is often a conflict between this outcome and the governmental obligation to address the needs of socio-economic issues, such as public health, nutrition and general well-being.

Dealing with these matters is not easy. Though the legal infrastructure to support the local biotech industry is available, that alone is not enough. Malaysia still faces other problems, including insufficiencies in skilled workers, physical and technological infrastructure, as well as other special requirements for the unique needs of the industry. Moreover, any adverse legal or policy decision by the Government would have a collective impact on the nation's aspirations of becoming a biotech producer. For example, the decision to exclude a perfectly eligible biotech invention from patent protection on morality or *ordre public* grounds can be discouraging to the technology producing community.[6]

Further, if Malaysia heightens the patentability standard, as preferred by the developed nations, this would make it too difficult for local biotechnologists to obtain patents. Technologically, local biotechnologists are not on par with their foreign counterparts. Heightened protection standards would defeat the original purpose of encouraging local participation in the development of the biotechnology industry. In order to stay competitive and fulfil national aspirations, Malaysia must continuously improve its domestic system to overcome any shortcomings.

Patentability and TRIPS: biotech law and policy

Article 27 of TRIPS does not specifically mention the term 'biotech invention'. Nonetheless, the term 'in all fields of technology' is sufficiently inclusive to cover biotech inventions. Unlike in the past[7], all WTO Members must now provide for the legal protection of biotech inventions.

Patent protection for biotech inventions is valid for 20 years. The limited monopoly right acts provide a financial incentive for innovation. Biotechnologists can protect, commercialize and profit from their inventions. The potential to recoup and attain returns in excess of the initial investment is

[5] In Malaysia, the term 'utility model' refers specifically to petty patents as they are known in other jurisdictions. These are granted to innovations with a lesser inventive step than those required for patent protection.

[6] As a multiracial Muslim country, it is foreseeable that the patent office or court of Malaysia would potentially reject applications for the patenting of a biotechnological invention, for instance those containing DNA of swine.

[7] In the past, countries have had absolute liberty not to grant patent protection to biotechnological inventions or if agreeable, to grant a limited protection to the biotechnological invention, through process patents. This is despite the patentability of the subject matter or eligibility for protection through both process and product patents.

essential. This is especially so in cases where R&D expenses are significant and where government funding is unavailable or scarce. These initial expenditures are required in order to satisfy the stringent experimental requirements and regulations set by government agencies to ensure that biotech products are safe and suitable for consumers.

Owing to the nature of biotechnological inventions, they stand a relatively greater chance of obtaining process and product patents[8] than other inventions. A biotech invention is patentable if it is novel[9], has an industrial application[10], and is non-obvious.[11] The standardized patentability requirements are applicable in every Member country of the WTO. The universally applicable standards of the TRIPS Agreement assist biotechnologists in predicting the potential success rate of patenting their inventions in every jurisdiction, where the TRIPS Agreement applies. For example, based on an application in one jurisdiction, the rights holder is better equipped to anticipate the problems he may encounter in another jurisdiction. Such harmonized patentability requirements at an international level are useful and reassuring to the biotech community. They help to reduce costs and save time.

Malaysia as a biotech producer

Biotech law is relatively new to Malaysia. Nevertheless, if Malaysia fully capitalizes on the provisions of Article 27 of the TRIPS Agreement, the country could finally become a significant player in the field. In spite of their diverse backgrounds, Members of the WTO pledged their support for the transfer of technology from developed to developing markets, as well as the promotion of trade and economic development in all Member States.[12]

Malaysia is one of the guardians of the world's largest forests and natural heritage. It has a potentially limitless source of genetic materials that may be extracted from its rich flora and fauna. These are the raw materials that are commonly used in biotechnological inventions. As a source country, Malaysia's free and direct access to these raw materials gives it an advantage over its more developed counterparts. This advantage facilitates cost savings, especially those relating to importation. Malaysia could also export genetic materials and finished products. There is also a possibility for licensing the technology internationally. This would generate new sources of income for the country.

Recent governmental policies demonstrate a clear shift in this direction. Malaysia's intention to become a regional biotech industry hub was first announced in 2005.[13] The plan revealed the

[8] Article 27 of the TRIPS Agreement requires that every Member country grant patent protection to inventions in all fields of technology, for both processes and products. Since biotechnological inventions are usually both, they stand a better chance of obtaining both types of protection than inventions in other fields of technology.

[9] Article 27 of the TRIPS Agreement.

[10] Depending on jurisdictions, the 'industrial applicability' criterion is interchangeably used with' 'useful', For example countries subscribing to the European Patent Convention use the term 'industrial applicability' whereas the US patent law uses the term 'useful'.

[11] The term is interchangeably used with 'inventive step'. See the footnote to Article 27 of the TRIPS Agreement or domestic patent laws worldwide.

[12] Article 7 of the TRIPS Agreement.

[13] As announced in the National Biotechnology Policy 2005.

Government's intention to eventually shift the country's economic base from agriculture and manufacturing to a knowledge and innovation-based economy.[14]

Under the Ninth Malaysian Plan (2006-2010), the Government allocated an annual budget of nearly $1 billion for the biotech industry. The industry received the most attention and the largest financial allocation compared to other industries. Accordingly, $400 million was used for business development, followed by $350 million for research and development. The balance was used for biotech infrastructure. These efforts should make Malaysia an attractive hub for the biotech industry. The Government envisaged that the biotech field would be the next engine for Malaysia's economic growth, accelerating the nation's goal of transforming itself into a highly industrialized nation by the year 2020.

Characteristics of biotech inventions

Compared with other inventions, biotech has unique characteristics that differentiate it from other fields of technology. It also has limitless potential and can be used in a wide array of areas and industries, ranging from food to cosmetic products and processes. This versatility provides for promising and lucrative business ventures. Understanding these characteristics is useful for any party or country interested in venturing into biotechnology industry.

Modern biotech is different from its historical form. Conventional biotechnology relied heavily on cross-breeding techniques to physically transfer genetic templates for the propagation of new plant varieties, crops, or animals of the same species. For instance, cross breeding a horse and mule produces a donkey.

Conventional biotechnology is generally not eligible for patent protection due to lack of human and technological interference. Inventors are then unable to satisfy the novelty criteria for patents.

In contrast, modern biotech operates at the genetic and molecular levels. It revolves around the manipulation and alteration of DNA (deoxyribonucleic acid), the genetic make-up of every living organism. Any portion or fragments of DNA from similar or different sources may be cut, re-joined or inserted to make novel sequences of DNA. The new DNA can be manipulated to perform certain functions, such as producing cells and proteins for medicinal and pharmaceutical purposes.

Hypothetically, biotechnologists can extract a particular DNA strand from a dragon fly and combine it with the DNA of a maize crop to produce bioluminescent maize. Such breeding across species was impossible in the past. Owing to the ability to manipulate genes at the molecular level, modern biotech tends to be more patentable, as it is more likely to satisfy the criteria for protection.

One of the many other uses of biotech processes is in providing a conduit for carrying foreign genes or DNA into host organisms or cells. The end result of this process can be patented. Unlike other engineering inventions, the end product of biotech inventions can appear in the form of living organisms, plants and animals. These are often referred to as transgenic organisms. Chakrabathy's bacterium[15] and the Harvard Onco-mouse[16] are good examples.

[14] As announced by the Prime Minister in 2006 and 2009.
[15] *Diamond* v. *Chakrabathy*. US S. Ct. 1980 447 U.S. 303, 100 S. Ct 2204 65 L.Ed. 2d, 206 USPQ 193.
[16] T19/90, Harvard/Onco-Mouse, [1990] E.P.O.R. 501, 503 (Technical Board Appeal, 1990).

In some cases, biotech can be regarded as a pure science. In this context, related theories or scientific principles discovered during the course of research do not constitute patentable subject matter, regardless of their novelty. However, as an applied science, biotechnology inventions provide value, which benefits the public due to their ability to solve real life problems. As inventions with real life applications, biotechnological inventions may be patented.

The demarcation between biotech as a pure versus applied science is often blurred. As a result, biotechnologists face difficulties in convincing patent offices and the courts that their inventions possess the practical utility necessary for a patent award. The very philosophy of patent law prevents inventors from excluding others from areas which are of no legitimate use to the inventor.[17] If barring patent protection on the basis of usefulness were permissible, this would chill the future of the Malaysian biotech industry. The biotechnologist needs patent protection to continue his research, which will ultimately facilitate the discovery of its full utility and development.

Biotech inventions are highly technical and complicated. This is because biotechnologists attempt to mimic the natural processes of life by manipulating the cellular systems of living organisms. They rely heavily on access to biological materials, and invest significant amounts of money, labour and time to discover and characterize their functions.

Biotechnologists have to embark on lengthy and delicate processes of extracting the desired molecules. Such procedures are like casting a magnet blindingly into an enormous haystack, hoping to retrieve a needle that may not be there at all. If successful, the biotechnologist's job does not end there. Not only are the genetic materials invisible to the naked eye, they are also embedded within minute volumes of matter that are mingled with other materials without any biotechnological significance.

Once these molecules have been isolated, highly sensitive tools are used in a series of equally sophisticated investigative procedures to ascertain, obtain and manipulate those tiny molecules with the hope of finally producing the desired result. Consequently, it makes biotech a material-intensive field of research, perhaps more than other areas of technology.

The properties of many genes, DNA or cells are still poorly understood or remain completely unknown.[18] Therefore, biotech inventions are known for their unpredictability. This hampers any efforts to proceed with ascertaining, obtaining, manipulating or identifying the characteristics, functions and uses of resultant inventions. In fact, these are regarded as the most significant challenges faced by biotechnologists and scientists in general.

The problems of identifying a molecule’s utility are heightened by the frequent use of host or recipient cells to express foreign biological materials.[19] When injected with genetic material from other organisms, the host cell may have a negative response to the introduction of foreign molecules. Nature has programmed cells to recognize only their own cells and to reject alien elements. They may start building up antibodies, which under normal circumstances, are designed to defend them against

[17] *Brenner* v. *Manson,* 1966, page 566.
[18] Ibid.
[19] Ibid.

foreign or defective native proteins.[20] Their natural enzymes may then attack and degrade the unfamiliar biotech product.[21]

So far, biotechnologists have been unable to ascertain or fully understand all the complex possible linkages in cellular chemical reactions. It is feared that alterations to structures, such as amino acid sub-units in a protein, may have unforeseen and undesirable side effects to humans.[22] Feedback mechanisms within an organism invariably cause changes in one chemical process, which could also affect other processes.[23]

With limited knowledge, it is almost impossible for biotechnologists to clearly understand the different processes that occur within a single human cell, including how multiple signals occur and the interaction of genes.[24] Biotechnologists are working towards the development and refinement of the existing techniques to make them more effective. Hopefully, this will eventually decrease the unpredictability of the results, thus allowing advances in knowledge, technology and the discovery of new frontiers. However, even when certain procedures become more predictable and precise, it is still possible that scientists may stumble upon complexities in other areas.[25]

The importance of human resources capacity building

The characteristics of biotech inventions and the related challenges, as discussed above, have a direct impact on Malaysia's intention and capabilities for becoming a major biotech producing nation. As stated earlier, the understanding and insights of the characteristics of the biotech industry would help interested parties to identify their strengths and weakness as part of their long-term preparation before venturing into this industry.

For example, owing to their lack of technological knowledge and capabilities, biotechnologists may need to delay or postpone their patent applications. It would be better for them first to conduct further research to identify the utility and capabilities of their biotechnological processes or products. Otherwise they may not be able to satisfy the patentability requirements.

Without a solid understanding of the potential utility and capabilities of their inventions, biotechnologists may be unable to ascertain the fate of their patent applications or accurately predict the corresponding scope of protection until the result is finally announced by the patent office or the courts. Such uncertainty is not conducive for business. Inevitably these technical obstacles may cause delays in the patent process and in the dissemination of knowledge to the public. It also impedes the development of the biotech field and the marketing of biotech products.

[20] Ibid., page 91.
[21] Ibid., page 94.
[22] Ibid.
[23] Ibid.
[24] For example, in a protein, constructed of hundreds amino acid sequences, a single amino acid change can dramatically alter the shape of a protein, nullifying the protein's original function or creating an entirely new function.
[25] See footnote 13.

Characteristics of the Malaysian biotech industry

The Malaysian biotech landscape

The Malaysian biotech industry is less than ten years old. Moreover it has different characteristics from those of nations with established technology sectors. Therefore, Malaysia is likely to encounter different technical challenges in achieving its aspiration of becoming a regional biotech centre. Understanding the characteristics of the local biotech industry is necessary in helping the nation to counter these challenges and provide for optimal patent-biotech laws and policies.

The Malaysian biotech sector is dominated by privately owned family business entities operating as partnerships or private companies. Another group of players include public and transnational companies operating within the country. There are also other entities, such as government-linked companies. To a certain extent, the nature, size and people behind the entities in this industry influence the way in which the biotech business is conducted.

For example, a Chinese biotech family business may prefer to adopt the Chinese business philosophy in running its business. The proprietors may prefer to keep the business amongst family members. Specifically, they may be unwilling to open investment to strangers, or to share the patent rewards with biotechnologists and researchers that are unrelated to them. This approach may not necessarily be optimal for the biotech industry.

Biotech businesses in Malaysia also differ in their financial resources. Generally, the annual budgets and corresponding profits of the companies tend to be small. Family businesses usually obtain their funding from the owners' personal resources or through loans. Typically, start-up companies linked to the Government usually receive considerable sums of working capital from the State until they become financially independent.

Though there are companies scattered all over the country, most are concentrated in Kuala Lumpur and Selangor. These are the most populous and developed parts of the country. Some of these companies establish their headquarters and run their businesses from the capital, while locating their research centres and manufacturing plants elsewhere.

This situation affects companies' ability to hire and retain qualified experts, such as researchers or biotechnologists for their manufacturing plants. Some of these experts prefer to live and work in the capital because of the associated facilities and lifestyle benefits. Some are willing to commute to the research centres or manufacturing plants on a periodic basis, provided their employers bear all expenses incurred. At the same time, some prefer to work outside of the capital due to the lower cost of living and family attachments.

These factors are partially responsible for the high turnover rates amongst skilled employees. Incidentally, biotech companies are constantly vulnerable to local labour supply issues. Many take a long time to fill their vacancies. This delays the work process and unnecessarily increases costs.

Malaysia has achieved a considerable level of economic development. It is not far behind the developed nations in terms of physical and technological infrastructure. The country has a good transportation system, ICT infrastructure, a well-structured education system and a large, strong, and competitive labour supply. Some of these basic facilities are equivalent to those of developed nations.

Unlike other developing countries, for the most part, these facilities are equally distributed throughout the nation. Theoretically, Malaysia could easily succeed in its latest endeavour in becoming a regional or international biotech hub.

However, since biotech is relatively new to Malaysia, most local companies are young. Apart from the transnational companies, on average, many of them have less than five years' experience in the industry. Further, most were previously technology users and had little or no experience as technology producers. It is unsurprising that many have yet to build solid R&D facilities or produce their first biotech inventions, let alone patent them. In terms of advanced technological knowledge and expertise, Malaysia lags far behind its more developed counterparts and other emerging economies, such as India and Chinese Taipei.

Intellectual property-related barriers to expansion of the biotech industry in Malaysia

Malaysian biotech companies are often forced to rely completely on data from abroad, which are usually protected by patents. Access to such knowledge or the latest technology is only possible by way of licensing, which tends to involve expensive royalties. This fact is validated by the number of domestic patent applications for biotech inventions. For example, as of July 2009, there had been 262 patent applications filed by locals, and 1561 by foreigners. Yet, of these, only eight local inventions were eligible for patent protection compared with 501 for foreign biotechnologists.[26] Many of the local biotech inventions are more suitable for utility model protection.

There are some basic local research programmes that are currently conducted independently, or as part of a collaborative effort with research institutions and State universities. It is still uncertain whether these efforts will bear the desired fruits in the near future.

The expense of licensing fees and royalties is a major strain on Malaysian biotech companies. Since these fees are largely determined by the technology producer, local businesses may find these payments beyond their means. Alternatively, the companies could invest in their own R&D programmes. Regardless of which option they choose, the rate of technological development and progression becomes more expensive and much slower than anticipated. This may mean that the Malaysian biotech industry will take a long time to fully blossom.

Financing barriers to the development of the Malaysian biotech industry

Despite its limitless potential for financial rewards, biotech is an expensive and burdensome undertaking. As a complex, highly technical and research-based field, it requires high initial investments to fund overlapping experiments and research before an end product can be successfully produced. Only wealthy corporations or advanced countries can accumulate the necessary capital[27] through the stock markets or other private and public funding mechanisms. Therefore, Malaysian biotech companies are yet to achieve the stature of their developed country counterparts in providing similar funding allocations to their R&D programmes.

Even though there are various governmental financing incentives, including loans and grants for biotech companies, these amounts are quite modest. Furthermore, owing to insufficient publicity, many of the local biotech companies are unaware of the available governmental assistance. When

[26] As at July 2009, Patent Office of Malaysia.
[27] For developing or furthering research.

they are, many are not eager to take it up. The reasons range from the unwillingness to navigate administrative bureaucracies, ineligibility, the lack of necessary documentation, and a discomfort with allowing government officers to monitor their activities to ensure that there is no fraud or misuse of the funds provided. The lack of funds limits the type and amount of research that Malaysian biotechnologists can conduct. This, in turn, affects the quality of their biotech end products.

The shortage of skilled labour in the Malaysia biotech industry

It can be observed from biotech litigation in developed nations, that most biotechnologists and genetic engineers are highly qualified. They either have doctorates or several years of work experience at research institutes and universities. In contrast, Malaysia still faces a shortage of highly skilled technical labour, such as biotechnologists, scientists, engineers and other professionals with relevant skills and capabilities. This shortage affects other industries beyond biotech.

Though skilled technical labour, such as laboratory assistants, research officers and IT officers have secondary roles in supporting biotechnologists and the biotech industry, their functions should not be ignored or under-estimated. They are increasingly pivotal in the overall biotech programme. In certain instances, shortfalls in skilled technical support staff actually stands between the biotechnologist and his prized goal. For example, they are critically needed to work as patent examiners in patent offices. Upon the submission of a patent application, they would know what to look for without being unduly influenced by the technicalities of an invention, which may mislead them into assuming its patentability. Since the Malaysian Patent Office and judiciary are mostly new to the biotech industry and lack the necessary experience in determining patentability requirements, developing a technically competent labour pool is an important goal.

Malaysia lacks engineering and science graduates generally, and biotech specifically. It needs more than a tenfold increase in these areas in order to achieve the same proportions as Singapore, South Korea, and Chinese Taipei.[28] This can be attributed to several reasons. First, since modern biotech is relatively a young field of knowledge, not many university graduates in Malaysia take it up as their potential career path. Additionally, not all local universities have a biotech faculty or offer it as a subject.

This problem is deeply intertwined with the exodus of skilled labour moving abroad in search of better prospects. Malaysia could try to entice foreign experts to work in the country with the objective of training locals. This effort would likely be worthless due to its temporary nature. Malaysia could also send existing local experts abroad to enhance their knowledge on a regular basis. Again, this is a short-term solution which would be impractical in the long term because it involves a large amount of money being invested in a select few. There is also no guarantee that these local experts will return once they have completed their training abroad. Further, if they do return, there is the possibility that they might not be able to keep up with the rapid pace of technological advancement. Most likely, by the time they return to use or teach others their new knowledge and skills, new technological developments may have outpaced them.

However, reforms are under way to address these weaknesses within Malaysia's higher education sector. These efforts have been embodied in the National Higher Education Strategic Plan 2007-2010 and the National Higher Education Action Plan 2007-2010. Such a goal cannot be

[28] *Building Knowledge Economies. Advanced Strategies for Development,* World Bank Institute, (Washington D.C., 2007), pp. 30-33.

achieved overnight. It may require at least five to ten years to determine whether these efforts bear fruit.

Legal and policy reforms in the Malaysian biotechnology sector

Because of the unique characteristics of the Malaysian biotech industry, Malaysia is unlikely to adopt the same approach for biotech laws and policies as countries with established technology development sectors. Historically, technology-producing nations adopted a strong and extensive patent law protection regime. This has been traditionally associated with higher profitability through sales, licensing fees and royalties. Such an approach is not suitable for Malaysia. The broader scope of protection preferred by technology producers makes access to protected information more expensive and difficult to obtain than before.

If Malaysia is to follow in the footsteps of technologically advanced nations in awarding more extensive patent protection, this would be likely to have adverse effects for the future of the country's emerging biotech industry. Access to patented technological knowledge would be limited, as it would be based on the modest financial capabilities of local biotechnologists. Technology transfer and development would become more expensive and costly. At the same time, taking into consideration the nature of the biotech industry and the technological capabilities of local companies, Malaysia should also carefully consider whether it wants to adopt a higher or lower standard for patentability. It must be noted, however, that more relaxed patent laws than those of more advanced countries are permissible as long as they do not fall below the minimum standards set by the TRIPS Agreement.[29]

Patentability requirement: policy issues

It has been more than ten years since the TRIPS Agreement came into force. Although Malaysia has duly amended its current *Patent Act, 1983* to conform to the Agreement, the country is yet to define fully its domestic biotech patent laws and policy. There are still a few issues pertaining to biotechnological inventions that remain unclear. Strategically, Malaysia should take advantage of the TRIPS flexibilities to formulate competitive biotech laws and policies. The timing is also perfect since the Government is currently reviewing and amending the existing *Patent Act*. In so doing, the Government needs to ensure that the intended reforms strike a balance between attracting foreign investment, while protecting and promoting local technological progress.

One specific deficiency in this regard is the definition and standard of 'novelty', one of the three requirements for patentability. Unfortunately there is no existing definition and standard of novelty for biotech inventions in Malaysia. The only available definition of novelty is extracted from the field of electrical and mechanical inventions[30], which involve non-living and purely mechanistic inventions. Considering the characteristics of biotech product as, *inter alia*, a living invention, the same definition may not be suitable or appropriate for the biotech field.

In terms of novelty for biotechnological inventions, Malaysia should define the term in a more stringent manner than the definitions adopted by developed nations.[31] This is to ensure that only

[29] Article 1 of the TRIPS Agreement.

[30] *Rhone-Poulene Ag and Anor* v. *Dikloride Herbicides Sdn. Bhd*. (1988) 2 Malayan Law Journal 323.

[31] *Dennis* v. *Pitner 106 F.2nd 142 (7th Cir. 1939). 106, Diamond* v. *Chakrabathy. US S. Ct. 1980 447 U.S. 303, 100 S. Ct 2204 65 L.Ed. 2d, 206 USPQ 193, Ex Parte Latimer. 1889 Dec. Comm'r Pat. 123. (1889), Kuehmsted v. Farbenfabriken of Elberfeld Co., 179 F. 701 (7th Cir. 1910), cert. denied, 220 U.S. 622 (1911), Parke-Davis and Co.* v. *H.K. Mulford & Co. 196 F. 496 (2d. Cir. 1912).*

meritorious inventions are awarded patents. At a glance this suggestion may appear to be contradictory and running counter to the nation's intent in supporting its emerging biotech industry. Admittedly, strengthening the definition of novelty would make it harder for local biotechnologists to satisfy the novelty requirement. Therefore, the most logical answer appears to be a looser definition of novelty that is easier to satisfy. Yet such choice would lead to the patenting of many trivial inventions, which may potentially become the subjects of licensing fees and royalties. In that sense, the public would be short-changed as it would have to pay for 'inventions' that could be considered as banal technological knowledge.

In the long term, the public domain would be littered with low quality technological knowledge. This would naturally discourage new players from engaging in innovative activities. Instead of using and focussing their limited resources on R&D, many would be embroiled in issues of negotiation, licensing fees and the payment of royalties. These matters would only delay and increase the costs of technology transfer in the local biotech industry. Given the aforementioned arguments, a more stringent definition of novelty is preferable. It would encourage local biotechnologists to produce high quality inventions.

The proposed novelty provision could stipulate that 'an invention shall be deemed to be new when it does not form part of the state of the art, which comprises all knowledge made available to the public in any country by any means of a written or oral description, by use or in any way'. Such language is loosely based on Article 54 of the *European Patent Convention, 1973* (EPC).

Such a model would prevent the patenting of unpublished inventions or those based on pre-existing traditional or indigenous knowledge. The relevant provision could stipulate that 'the state of art shall include unpublished patent applications filed at the national patent office, where such applications are subsequently published.' Such a provision is believed[32] to be broad enough to include knowledge developed by, or in possession of local or indigenous communities. This exclusion clause could be accompanied by a supplementary clause stating that local and indigenous knowledge would be protected outside the patent law regime. For example, this could be done under a separate *sui generis* scheme.

The issue of novelty is especially significant. As explained further in the following paragraphs, the recommended provisions would eliminate the novelty of any proposed patent once there was a disclosure anywhere in the world. This would be the case regardless of whether the disclosure was made orally, in written or other forms. Principally this is something Malaysia could do for local indigenous communities[33] or for those from other parts of the world. Since Malaysia is disapproving when developed nations patent their indigenous knowledge or inventions, the nation should have no desire to do the same to others.

Flexible versus absolute novelty

It is reported that the Patent Office will soon be flooded with foreign and local biotech patent applications. At the time of this writing, it is also anticipated that the Patent Office and the courts shall encounter problems pertaining to the novelty requirement. So far, there are no local judicial decisions

[32] C. Correa, 'Implementing the TRIPS Agreement in the patents field: options for developing countries. *Journal of World Intellectual Property, 1*, (2003), 75-92.

[33] Malaysia has more than 50 known indigenous tribes.

that could assist the patent office and other interested parties to enhance their understanding of the parameters of this requirement.

For reasons to be explained below, it would be better for Malaysia to maintain the concept of absolute novelty in determining patentability. The concept preserves novelty by demanding absolute secrecy and non-disclosure of any kind before the patent filing. Regardless of whether the disclosure was made intentionally or inadvertently, the invention is rendered permanently ineligible for a patent.

Admittedly, absolute novelty has its disadvantages. Not only does it make the novelty requirement harder to satisfy, there is also a chance that biotechnologists would lose the patent race to their counterparts elsewhere. For example, any pre-patent disclosure of an invention, such as publication in academic journals or an oral presentation at a seminar anywhere in the world, would compromise novelty and deny patent protection for the invention.

Absolute novelty is a higher and stricter standard than the standard of flexible novelty as practised in the American patent system. Flexible novelty accepts certain public disclosures of the invention that are regarded as non-destructive to novelty. Novelty is preserved as long as the inventor abides by certain legally stipulated requirements. Thus, it makes the novelty requirement easier to satisfy than in absolute novelty jurisdictions. However, this may permit some parties to 'hijack' the unwritten works of others in foreign jurisdictions who would be the first to claim patent protection in their own countries, where flexible novelty prevails. Unlike in absolute novelty jurisdictions, their patent applications would not be denied on the grounds of novelty, even though the invention has been known or used by others in the country of initial disclosure.

Ideally, the decision to opt initially for flexible novelty in Malaysia may be appropriate as a short-term measure, until local biotechnologists are financially and technologically competent However, there is a risk that the patent office may in some instances grant patents for pre-existing knowledge or prior art, which is the benchmark upon which novelty is assessed. Legally, the novelty inquiry is limited to whether the invention has been revealed or made available to the public.[34] Thus, if the information regarding the invention is not known, revealed, communicated, patented, sold, used or described to the public, it is considered to have been previously unavailable to the public. This makes it new and patentable.

Despite factors in favour of Malaysia's adopting flexible novelty, it is still preferable for the country to adopt the absolute version of the standard. Arguably not all local biotechnologists would be able to satisfy the requirement**.** However, such a standard would encourage biotechnologists to be competitive, vigilant and expedient in filing their patent applications, so that their inventions can be disseminated at a faster rate.

Conclusion

In working towards achieving the national aspiration of becoming a biotech producer, Malaysia and local biotechnologists need urgently, aggressively and proactively to overcome their current financial, organizational and technological weaknesses.

Although the legal infrastructure necessary for supporting the biotech industry is present, the *Patent Act* is far from perfect. There are still legal policy issues, such as the definition of the novelty

[34] Article 54 of the *European Patent Convention*, Section 102 of the *US Patent Law*.

for patentability. Such a definition is very useful for biotech specifically. As a hybrid field, biotechnology stands between products of nature and human invention, thus blurring the distinction between what is patentable and what is not.

A strong IP legal infrastructure alone is insufficient for Malaysia's goal of becoming a global biotech centre. As new participants in the industry, local biotechnologists are still unfamiliar with the formal aspects of using and maximizing the benefits of the existing system. They may not know how to fill in the forms or where to submit them. It would save them time and significant costs if the Government or relevant office could introduce clear patenting guidelines. These guidelines would be equally useful for the Patent Office, examiners, and patent applicants.

In advancing towards becoming a biotech-producing nation, Malaysia should also focus on encouraging local biotechnologists to apply for patent protection under the existing utility model system.[35] By encouraging new and less experienced local biotechnologists to apply for utility model protection, they stand a better chance of enjoying financial rewards than they could through patent protection. This is because the requirements for utility models are less stringent. Further, local biotechnologists face a higher failure rate in patent applications than their foreign counterparts. By making utility model protection more available in Malaysia, the country could avoid creating a parallel regime with lower standards for the patentability of local inventions. The latter option could trigger discrimination challenges under Article 27 of the TRIPS Agreement. Naturally, the utility model scheme must be equally available to foreign applicants.

Malaysia must work to create a better organized system in its Patent Office. There is a need to provide for a separate patent examination office and another for utility models. The officers need to enhance their collaboration with one other, for example in identifying eligible applications, tracking their movement through the system and properly recording final decisions made on all files. If this is not done, they may grant more than one IP right over the same technology, or improperly reject an eligible invention.

The proposed system is consistent with the TRIPS Agreement. Though the legal protection offered by utility models is lower than that provided by patents, it is nonetheless legal and enforceable. In sum, the above recommendations would reduce the wariness felt by local biotechnologists, who are concerned about competing with their more established foreign counterparts. This would permit them to focus confidently on the level of R&D that corresponds with their resources.

In conclusion, Malaysia and its biotechnologists need to address their weaknesses and strengthen their capabilities, in order to face the challenges in becoming internationally competitive in the biotech industry.

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[35] A similar provision can be found in the *Patent Act 1983*, Section 17-17C. The other patent protection mechanism is the *Plant Variety Protection Act 2005*.

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